Form Approved. O.M.B. Nos. 2070-0012 and 2070-0038

U.S. ENVIRONMENTAL PROTECTION AGENCY			AGENCY USE ONLY	
EPA	PREMANUFACTURE NOTICE FOR NEW CHEMICAL SUBSTANCES		Date of receipt:	07/08/2019
When completed, send this form to:	If sending by Courier: Office of Pollution Prevention and Toxics Document Control Office (7407M) US EPA, 1201 Constitution Ave NW WASHINGTON, D.C. 20460 Contact Numbers: 202-564-8930/8940	If sending by US Mail: Office of Pollution Prevention and Toxics Document Control Office (7407M) US EPA, 1200 Pennsylvania Ave NW WASHINGTON, D.C. 20460	Submission Report Number	

Total Number of Pages	User Fee Payment ID Number	TS Number
18	Z546UT	

GENERAL INSTRUCTIONS

- You must provide all information requested in this form to the extent that it is known to or reasonably ascertainable by you. Make reasonable estimates if you do not have actual data.
- Before you complete this form, you should read the "Instructions Manual for Premanufacture Notification" (the Instructions Manual is available from the Toxic Substances Control Act (TSCA) Information Service by calling 202-554-1404, or faxing 202-554-5603).
- If a user fee has been remitted for this notice (40 CFR 700.45), indicate in the boxes above the TS-user fee identification number you have generated. Remember, your user fee ID number must also appear on your corresponding fee remittance. For mailing address information see the Help instructions in the e-PMN tool.

Part I – GENERAL INFORMATION

You must provide the currently correct Chemical Abstracts (CA) Name of the new chemical substance, even if you claim the identity as confidential. You may authorize another person to submit chemical identity information for you, but your submission will not be complete and the review will not begin until EPA receives this information. A letter in support of your submission should reference your TS user fee identification number. For all Section 5 Notice submissions (paper or electronic) you must submit an original notice including all test data; if you claimed any information as confidential, an original sanitized copy must also be submitted.

Part II – HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

If there are several manufacture, processing, or use operations to be described in Part II, sections A and B of this notice, reproduce the sections as needed.

Part III – LIST OF ATTACHMENTS

For paper submissions, attach additional sheets if there is not enough space to answer a question fully. Label each continuation sheet with the corresponding section heading. In Part III, list these attachments, any test data or other data and any optional information included in the notice.

OPTIONAL INFORMATION

You may include any information that you want EPA to consider in evaluating the new substance. On page 11 of this form, space has been provided for you to describe pollution prevention and recycling information you may have regarding the new substance. "Binding" boxes are included throughout this form for you to indicate your willingness to be bound to certain statements you make in this section, such as use, production volume, protective equipment . . . The intention is to reduce delays that routinely accompany the development of consent orders or Significant New Use Rules. Checking a "binding" box in a PMN does not by itself prohibit the submitter from later deviating from the information (except chemical identity) reported in the form; however, in the case of exemption applications (such as TMEA, LVE, LOREX) certain information provided in such notifications is binding on the submitter when the Agency approves the exemption application, especially if the production volume "binding" box is chosen in a LVE.

CONFIDENTIALITY CLAIMS

You may claim any information in this notice as confidential. To assert a claim on the form, mark (X) the confidential box next to the information that you claim as confidential. To assert a claim in an attachment, circle or bracket the information you claim as confidential. If you claim information in the notices as confidential, you must also provide a sanitized version of the notice, (including attachments). For additional instructions on claiming information as confidential, read the Instructions Manual.

TEST DATA AND OTHER DATA

You are required to submit all test data in your possession or control and to provide a description of all other data known to or reasonably ascertainable by you, if these data are related to the health and environmental effects on the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance. Standard literature citations may be submitted for data in the open scientific literature. Complete test data (written in English), not summaries of data, must be submitted if they do not appear in the open literature. You should clearly identify whether test data is on the substance or on an analog. Also, the chemical composition of the tested material should be characterized. Following are examples of test data and other data. Data should be submitted according to the requirements of §720.50 of the Premanufacture Notification Rule (40 CFR Part 720).

Test Data (Check Below any included in this notice)

☐	Environmental fate data	☐	Other Data
X	Health effects data	☐	Risk Assessments
☐	Environmental effects data	☐	Structure/activity relationships
X	Physical/Chemical Properties (A physical and chemical properties worksheet is located on the last page of this form.)		
☐	Test data not in the possession or control of the submitter		

TYPE OF NOTICE (Check Only One)

X	**PMN** (Premanufacture Notice)
☐	**SNUN** (Significant New Use Notice)
☐	**TMEA** (Test Marketing Exemption Application)
☐	**LVE** (Low Volume Exemption) @ 40 CFR 723.50(c)(1)
☐	**LOREX** (Low Release/Low Exposure Exemption) @ 40 CFR 723.50(c)(2)
☐	**LVE** Modification
☐	**LOREX** Modification
☐	**Mock Submission**
☐	Mark (X) if pending Letter of Support
N	IS THIS A CONSOLIDATED PMN (Y/N)?
1	# of chemicals or polymers (Prenotice Communication # required, enter # on p. 3).
X	Mark (X) if any information in this notice is claimed as confidential.

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The public reporting and recordkeeping burden for this collection of information is estimated to average 93 hours per response. Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the Director, Collection Strategies Division, U.S. Environmental Protection Agency (2822T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed EPA Form 7710-25 to this address.

CERTIFICATION -- A printed copy of this signature page, with original signature, must be submitted with CD or paper submission.

I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate. I further certify that, pursuant to 15 U.S.C. § 2613(c), for all claims for protection for any confidential information made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that the person submitting the claim has:

(i) taken reasonable measures to protect the confidentiality of the information;

(ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law

(iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and

(iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. § 1001.

Additional Certification Statements:

If you are submitting a PMN, Intermediate PMN, Consolidated PMN, or SNUN, check the following **user fee** certification statement that applies:

☐ The Company named in Part I, Section A has remitted the fee of $2500 specified in 40 CFR 700.45(b), or

☐ The Company named in Part I, Section A has remitted the fee of $1000 for an Intermediate PMN (defined @ 40 CFR 700.43) in accordance with 40 CFR 700.45(b), or

☐ The Company named in Part I Section A is a small business concern under 40 CFR 700.43 and has remitted a fee of $100 in accordance with 40 CFR 700.45(b).

If you are submitting a **Low Volume Exemption (LVE)** application in accordance with 40 CFR 723.50(c)(1) or a **Low Release and Low Exposure Exemption (LoRex)** application in accordance with 40 CFR 723.50(c)(2), check the following certification statements:

☐ The manufacturer submitting this notice intends to manufacture or import the new chemical substance for commercial purposes, other than in small quantities solely for research and development, under the terms of 40 CFR 723.50.

☐ The manufacturer is familiar with the terms of this section and will comply with those terms; and

☐ The new chemical substance for which the notice is submitted meets all applicable exemption conditions.

☐ If this application is for an LVE in accordance with 40 CFR 723.50(c)(1), the manufacturer intends to commence manufacture of the exempted substance for commercial purposes within 1 year of the date of the expiration of the 30 day review period.

				Confidential
Signature and title of Authorized Official (Original Signature Required)		Date		☐
	XXX		XXX	X

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Part I -- GENERAL INFORMATION

Section A – SUBMITTER IDENTIFICATION

Mark (X) the "Confidential" box next to any subsection you claim as confidential

1a.	Person Submitting Notice (in U.S.)					Confidential
Name of Authorized Official	(first) XXX		(last) XXX			X
Position	XXX					
Company	XXX					
Mailing Address (number & street)	XXX					
City		State		Postal Code	XXX	
email	XXX					

b.	Agent (if Applicable)					Confidential
Name of Authorized Official	(first) XXX		(last) XXX			X
Position	XXX					
Company	XXX					
Mailing Address (number & street)	XXX					
City	XXX	State	XXX	Postal Code	XXX	
e-mail	XXX		Telephone (include area code)		XXX	

c.	Joint Submitter (if applicable)					Confidential
If you are submitting this notice as part of a joint submission, mark (X)					☐	
Name of Authorized Official	(first)		(last)			☐
Position						
Company						
Mailing Address (number & street)						
City		State		Postal Code		
e-mail			Telephone (include area code)			

2.	Technical Contact (in U.S.)					Confidential
Name of Authorized Official	(first) XXX		(last) XXX			X
Position	XXX					
Company	XXX					
Mailing Address (number & street)	XXX					
City	XXX	State	XXX	Postal Code	XXX	
e-mail	XXX		Telephone (include area code)		XXX	

			Mark (X) if none	Confidential
3.	If you have had a prenotice communication (PC) concerning this notice and EPA assigned a PC Number to the notice, enter the number.		X	☐
4.	If you previously submitted an exemption application for the chemical substance covered by this notice, enter the exemption number assigned by EPA. If you previously submitted a PMN for this substance enter the PMN number assigned by EPA (i.e. withdrawn or incomplete).		Mark (X) if none X	Confidential ☐
5.	If you have submitted a notice of Bona fide intent to manufacture or import for the chemical substance covered by this notice, enter the notice number assigned by EPA.		Mark (X) if none X	Confidential ☐

6.	Type of Notice – Mark (X)						
1.	Manufacture Only ☐ Binding Option ☐	2.	Import Only X Binding Option X	3.	Both ☐		

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Part I – GENERAL INFORMATION -- Continued

Section B – CHEMICAL IDENTITY INFORMATION: You must provide a currently correct Chemical Abstracts (CA) name of the substance based on current CA index nomenclature rules and conventions.

Mark (X) the "Confidential" box next to any item you claim as confidential

Complete either item 1 (Class 1 or 2 substances) or 2 (Polymers) as appropriate. Complete all other items.

If another person will submit chemical identity information for you (for either Item 1 or 2), mark (X) the box at the right. Identify the name, company, and address of that person in a continuation sheet. ☐

1. Class 1 or 2 chemical substances (for definitions of class 1 and class 2 substances, see the Instructions Manual)

a. Class of substance - Mark (X)	Class 1	Class 2	CBI
	☐	☐	☐

b. Chemical name (Currently correct Chemical Abstracts (CA) Name that is consistent with TSCA Inventory listings for similar substances. For Class 1 substances a CA Index Name must be provided. For Class 2 substances either a CA Index Name or CA Preferred Name must be provided, which ever is appropriate based on current CA index nomenclature rules and conventions). ☐

CAS Registry Number (if a number already exists for the substance)

c. Please identify which method you used to develop or obtain the specified chemical identity information reported in this notice: (check one).

Method 1 (CAS Inventory Expert Service - a copy of the Identification report obtained from the CAS Inventory Expert Services must be submitted as an attachment to this notice) ☐	IES Order Number		**Method 2** (Other Source) ☐

Enter Attachment filename for Part I, Section B, 1. c. ☐

d. Molecular formula ☐

e. For a class 1 substance, provide a complete and correct chemical structure diagram. For a class 2 substance, provide a correct representative or partial chemical structure diagram, as complete as can be known, if one can be reasonably ascertained. ☐

Enter Attachment filename for Part I, Section B, 1. e. ☐

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For a class 2 substance - (1) List the immediate precursor substances with their respective CAS Registry Numbers. (2) Describe the nature of the reaction or process. (3) Indicate the range of composition and the typical composition (where appropriate).	Confidential

e. (1) List the immediate precursor substance names with their respective CAS Registry Numbers. ☐

Enter Attachment filename for Part I, Section B, 1. e. (1)		☐

e. (2) Describe the nature of the reaction or process. ☐

Enter Attachment filename for Part I, Section B, 1. e. (2)		☐

e. (3) Indicate the range of composition and the typical composition (where appropriate). ☐

Enter Attachment filename for Part I, Section B, 1. e. (3)		☐

Part I -- GENERAL INFORMATION – Continued

Section B -- CHEMICAL IDENTITY INFORMATION -- Continued

2. Polymers (For a definition of polymer, see the Instructions Manual.)	Confidential
a. Indicate the number-average weight of the lowest molecular weight composition of the polymer you intend to manufacture. Indicate maximum weight percent of low molecular weight species (not including residual monomers, reactants, or solvents) below 500 and below 1,000 absolute molecular weight of that composition.	X

Describe the methods of measurement or the basis for your estimates:

GPC ☐	**Other** (Specify Below) ☐	

Specify Other:

(i) lowest number average molecular weight:	(ii) maximum weight % below 500 molecular weight:	(iii) maximum weight % below 1000 molecular weight:
XXX	XXX	XXX

Enter Attachment filename for Part I, Section B, 2. a.	Sanitized Document: 3 Attach5_GPC_sanitized.pdf	X

b. You must make separate confidentiality claims for monomer or other reactant identity, composition information, and residual information. Mark (X) the "Confidential" box next to any item you claim as confidential

(1) - Provide the specific chemical name and CAS Registry Number (if a number exists) of each monomer or other reactant used in the manufacture of the polymer.
(2) - Mark (X) this column if entry in column (1) is confidential.
(3) - Indicate the typical weight percent of each monomer or other reactant in the polymer.
(4) - Choose "yes" from drop down menu if you want a monomer or other reactant used at two weight percent or less to be listed as part of the polymer description on the TSCA Chemical Substance Inventory.
(5) - Mark (X) this column if entries in columns (3) and (4) are confidential.
(6) - Indicate the maximum weight percent of each monomer or other reactant that may be present as a residual in the polymer as manufactured for commercial purposes.
(7) - Mark (X) this column if entry in column (6) is confidential.

Monomer or other reactant specific chemical name (**1**)	CBI (**2**)	Typical composition (**3**)	Include in identity (**4**)	CBI (**5**)	Max residual (**6**)	CBI (**7**)
XXX CAS Registry Number (**1**) XXX	X	XXX		X	XXX	X
XXX CAS Registry Number (**1**) XXX	X	XXX		X	XXX	X
XXX CAS Registry Number (**1**) XXX	X	XXX		X	XXX	X
XXX CAS Registry Number (**1**) XXX	X	XXX		X	XXX	X
XXX CAS Registry Number (**1**) XXX	X	XXX		X	XXX	X

Mark (X) this box if the data continues on the next page. ☐

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c. Please identify which method you used to develop or obtain the specified chemical identity information reported in this notice (check one).				CBI
Method 1 (CAS Inventory Expert Service - a copy of the identification report obtained from CAS Inventory Expert Service must be submitted as an attachment to this notice) [X]	IES Order Number	395702	**Method 2** (other source) [ ]	
Enter Attachment filename for Part I, Section B, 2. c.		Sanitized Document: 1 Attach1_IES_sanitized.pdf		[X]

d. The currently correct Chemical Abstracts (CA) name for the polymer that is consistent with TSCA Inventory listings for similar polymers.	[X]
XXX	

CAS Registry Number (if a number already exists for the substance)	XXX	

e. Provide a correct representative or partial chemical structure diagram, as complete as can be known, if one can be reasonably ascertained.	[X]
See Attachment (Sanitized Document: 2 Attach2_Structure_sanitiz...)	

Enter Attachment filename for Part I, Section B, 2. e.	Sanitized Document: 2 Attach2_Structure_sanitiz...	[X]

Part I -- GENERAL INFORMATION -- Continued

Section B -- CHEMICAL IDENTITY INFORMATION -- Continued

3. Impurities
   (a) - Identify each impurity that may be reasonably anticipated to be present in the chemical substance as manufactured for commercial purpose. Provide the CAS Registry Number if available. If there are unidentified impurities, enter "unidentified."
   (b) - Estimate the maximum weight % of each impurity. If there are unidentified impurities, estimate their total weight %.

Impurity (a)	CAS Registry Number (a)	Maximum Percent % (b)	Confi-dential
XXX	XXX	XXX	X
XXX	XXX	XXX	X

Mark (X) this box if the data continues on the next page. ☐

Enter Attachment filename for Part I, Section B, 3. ☐

4. Synonyms - Enter any chemical synonyms for the new chemical identified in subsection 1 or 2.
XXX

☒

Enter Attachment filename for Part I, Section B, 4. ☐

5. Trade identification - List trade names for the new chemical substance identified in subsection 1 or 2.
XXX

☒

Enter Attachment filename for Part I, Section B, 5. ☐

6. Generic chemical name - If you claim chemical identify as confidential, you must provide a generic name for your substance that reveals the specific chemical identity of the new chemical substance to the maximum extent possible. Refer to the TSCA Chemical Substance Inventory, 1985 Edition, Appendix B for guidance on developing generic names.

Terpolymer of Vinylidene fluoride, Tetrafluoroehylene and 2,3,3,3-Tetrafluoropropene,

Enter Attachment filename for Part I, Section B, 6.

7. Byproducts - Describe any byproducts resulting from the manufacture, processing, use, or disposal of the new chemical substance. Provide the CAS Registry Number if available.

Byproduct (1)	CAS Registry Number (2)	Confi-dential

Mark (X) this box if the data continues on the next page. ☐

Part I -- GENERAL INFORMATION -- Continued

Section C -- PRODUCTION, IMPORT, AND USE INFORMATION:

The information on this page refers to consolidated chemical number(s): [X] **1** [ ] **2** [ ] **3** [ ] **4** [ ] **5** [ ] **6**

Mark (X) the "Confidential" box next to any item you claim as confidential.

1. Production volume -- Estimate the **maximum** production volume during the first 12 months of production. Also estimate the maximum production volume for any consecutive 12-month period during the first three years of production. Estimates should be on 100% new chemical substance basis. For a Low Volume Exemption application, if you choose to have your notice reviewed at a lower production volume than 10,000 kg/yr, specify the volume and mark (x) in the binding box. If granted, you are bound to this volume.

Maximum first 12-month production (kg/yr) (100% new chemical substance basis)	Maximum 12-month production (kg/yr) (100% new chemical substance basis)	Confidential	Binding Option Mark (X)
XXX	XXX	[X]	[ ]

Enter Attachment filename for Part I, Section C, 1. | CBI [ ]

2. Use Information -- You must make separate confidentiality claims for the description of the category of use, the percent of production volume devoted to each category, the formulation of the new substance, and other use information. Mark (X) the "Confidential" Box next to any item you claim as confidential.

a. (1) --Describe each intended category of use of the new chemical substance by function and application.
(2) --Mark (X) this column if entry column (1) is confidential business information (CBI).
(3) --Indicate your willingness to have the information provided in column (1) binding.
(4) --Estimate the percent of total production for the first three years devoted to each category of use.
(5) --Mark (X) this column if entry in column (4) is confidential business information (CBI).
(6) --Estimate the percent of the new substance as formulated in mixtures, suspensions, emulsions, solutions, or gels as manufactured for commercial purposes at sites under your control associated with each category of use.
(7) --Mark (X) this column if entry in column (6) is confidential business information (CBI).
(8) --Indicate % of product volume expected for the listed "use" sectors. Mark more than one box if appropriate. Mark (X) to indicate your willingness to have the use type provided in (8) binding.
(9) --Mark (X) this column if entry(ies) in column (8) is (are) confidential business information (CBI).

Category of use (**1**) (by function and application i.e. a dispersive dye for finishing polyester fibers)	CBI (**2**)	Binding Option Mark (X) (**3**)	Production % (**4**)	CBI (**5**)	% in Formulation (**6**)	CBI (**7**)	% of substance expected per use (**8**)					CBI (**9**)
							Site-limited	Consumer*	Industrial	Commercial	Binding Option	
XXX	X		XXX	X	XXX	X	XXX	XXX	XXX	XXX		X

* If you have identified a "consumer" use, please provide on a continuation sheet a detailed description of the use(s) of this chemical substance in consumer products. In addition include estimates of the concentration of the new chemical substance as expected in consumer products and describe the chemical reactions by which this substance loses its identity in the consumer product.

Mark (X) this box if the data continues on the next page. [ ]

b. Generic use description — If you claim any category of use description in subsection 2a as confidential, enter a generic description of that category. Read the Instruction Manual for examples of generic use descriptions.

rubber products

Enter Attachment filename for Part I, Section C, 2. b. | CBI [ ]

3. Hazard Information -- Include in the notice a copy of reasonable facsimile of any hazard warning statement, label, material safety data sheet, or other information which will be provided to any person who is reasonably likely to be exposed to this substance regarding protective equipment or practices for the safe handing, transport, use, or disposal of the new substance. List in part III hazard information you include.

		Binding Option Mark (X)
Mark (X) this box if you attach hazard information.	[X]	[ ]

Part II-- HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

Section A -- INDUSTRIAL SITES CONTROLLED BY THE SUBMITTER

Mark (X) the "Confidential" box next to any item you claim as confidential

The information on pages 8 and 8a refer to consolidated chemical number(s): [X] **1** [ ] **2** [ ] **3** [ ] **4** [ ] **5** [ ] **6**

Complete section A for each type of manufacture, processing, or use operation involving the new chemical substance at industrial sites you control. Importers do not have to complete this section for operations outside the U.S.; however, you may still have reporting requirements if there are further industrial processing or use operations after import. You must describe these operations. See instructions manual

1. Operation description
   a. Identity -- Enter the identity of the site at which the operation will occur.

				Confi-dential
Name	XXX			
Site address (number and street)	XXX			[X]
City	XXX	County	XXX	
State	XXX	ZIP code	XXX	

If the same operation will occur at more than one site, enter the number of sites. Identify the additional sites on a continuation sheet, and if any of the sites have significantly different production rates or operations, include all the information requested in this section for those sites as attachments. →	XXX	[X]
Mark (X) this box if the data continues on the next page. [ ]		

b. Type -- Mark (X) Manufacturing [ ] Processing [ ] Use [ ] — [X]

c. Amount and Duration -- Complete 1 or 2 as appropriate

				Confi-dential
1. Batch	Maximum kg/batch (100% new chemical substance)	Hours/batch	Batches/year	[X]
	XXX	XXX	XXX	
2. Continuous	Maximum kg/day (100% new chemical substance)	Hours/day	Days/year	[ ]

d. Process description — Mark (X) to indicate your willingness to have your process description binding. → [ ]

(1) Diagram the major unit operation steps and chemical conversions. Include interim storage and transport containers (specify- e.g. 5 gallon pails, 55 gallon drum, rail car, tank truck, etc.).
(2) Provide the identity, the approximate weight (by kg/day or kg/batch on a 100% new chemical substance basis), and entry point of all starting materials and feedstocks (including reactants, solvents, catalysts, etc.), and of all products, recycle streams, and wastes. Include cleaning chemicals (note frequency if not used daily or per batch.).
(3) Identify by number the points of release, including small or intermittent releases, to the environment of the new chemical substance. If releasing to two media at the same step, assign a second release number for the second medium.

[X]

XXX

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Diagram of the major unit operation steps.	Confidential
	X

See Attachment (Sanitized Document: 7 Cover Letter with revised...
)

Enter Attachment filename for Part II, Section A, 1. d.	Sanitized Document: 7 Cover Letter with revised... X

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Part II-- HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE -- Continued

Section A -- INDUSTRIAL SITES CONTROLLED BY THE SUBMITTER -- Continued

The information on pages 9 and 9a refer to consolidated chemical number(s): [X] **1** [ ] **2** [ ] **3** [ ] **4** [ ] **5** [ ] **6**

2. Occupational Exposure -- You must make separate confidentiality claims for the description of worker activity, physical form of the new chemical substance, number of workers exposed, and duration of activity. Mark (X) the "Confidential" box next to any item you claim as confidential.

(1) -- Describe the activities (i.e. bag dumping, tote filling, unloading drums, sampling, cleaning, etc.) in which workers may be exposed to the substance.
(2) -- Mark (X) this column if entry in column (1) is confidential business information (CBI).
(3) -- Describe any protective equipment and engineering controls used to protect workers.
(4) and (6) -- Indicate your willingness to have the information provided in column (3) or (5) binding.
(5) -- Indicate the physical form(s) of the new chemical substance (e.g., solid: crystal, granule, powder, or dust) and % new chemical substance (if part of a mixture) at the time of exposure.
(7) -- Mark (X) this column if entries in columns (3) and (5) are confidential business information (CBI).
(8) -- Estimate the maximum number of workers involved in each activity for all sites combined.
(9) -- Mark (X) this column if entry in column (8) is confidential business information (CBI).
(10) and (11) -- Estimate the maximum duration of the activity for any worker in hours per day and days per year.
(12) -- Mark (X) this column if entries in columns (10) and (11) are confidential business information (CBI).

Worker activity (i.e., bag dumping, filling drums) (1)	CBI (2)	Protective Equipment/ Engineering Controls (3)	Binding Option Mark (X) (4)	Physical form(s) & % new substance (5)	Binding Option Mark (X) (6)	CBI (7)	# of Workers Exposed (8)	CBI (9)	Maximum Duration		CBI (12)
									Hrs/Day (10)	Days/Yr (11)	
XXX	X	XXX		XXX		X	XXX	X	XXX	XXX	X
XXX	X	XXX		XXX		X	XXX	X	XXX	XXX	X
XXX	X	XXX		XXX		X	XXX	X	XXX	XXX	X
XXX	X	XXX		XXX		X	XXX	X	XXX	XXX	X
XXX	X	XXX		XXX		X	XXX	X	XXX	XXX	X

Mark (X) this box if the data continues on the next page. [ ]

Enter Attachment filename for Part II, Section A on the bottom of page 9a. [ ]

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3. Environmental Release and Disposal -- You must make separate confidentiality claims for the release number and the amount of the new chemical substance released and other release and disposal information. Mark (X) the "Confidential" box next to each item you claim as confidential.

(1) -- Enter the number of each release point identified in the process description, part II, section A, subsection 1d(3).
(2) -- Estimate the amount of the new substance released (a) directly to the environment or (b) into control technology (in kg/day or kg/batch).
(3) -- Mark (X) this column if entries in columns (1) and (2) are confidential business information (CBI).
(4) -- Identify the media (stack air, fugitive air (optional-see Instruction Manual), surface water, on-site or off-site land or incineration, POTW, or other (specify)) to which the new substance will be released from that release point.
(5) -- a. Describe control technology, if any, and control efficiency that will be used to limit the release of the new substance to the environment. For releases disposed of on land, characterize the disposal method and state whether it is approved for disposal of RCRA hazardous waste. On a continuation sheet, for each site describe any additional disposal methods that will be used and whether the waste is subject to secondary or tertiary on-site treatment. b. Estimate the amount released to the environment after control technology (in kg/day).
(6) -- Mark (X) this column if entries in columns (4) and (5) are confidential business information (CBI).
(7) -- Identify the destination(s) of releases to water. Please supply NPDES (National Pollutant Discharge Elimination System) numbers for direct discharges or NPDES numbers of the POTW (Publicly Owned Treatment Works). Mark (X) if the POTW name or NPDES # is confidential business information (CBI).

Release Number	Amount of New Substance Released		CBI	Medium of release e.g. Stack air	Control technology and efficiency (you may wish to optionally attach efficiency data)			CBI
(1)	(2a)	(2b)	(3)	(4)	(5a)	Binding Mark (X)	(5b)	(6)
XXX	XXX	XXX	X	XXX	XXX		XXX	X

Mark (X) this box if the data continues on the next page. ☐

(7) Mark (X) the destination(s) of releases to water.		NPDES#	CBI
☐ POTW--provide name(s)			☐
☐ Navigable waterway- - provide name(s)			☐
☐ Other--Specify			☐

Enter Attachment filename for Part II, Section A. ☐

Part II-- HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE – Continued

Section B -- INDUSTRIAL SITES CONTROLLED BY OTHERS

The information on pages 10 and 10a refer to consolidated chemical number(s): [X] **1** [ ] **2** [ ] **3** [ ] **4** [ ] **5** [ ] **6**

Complete section B for typical processing or use operations involving the new chemical substance at sites you do not control. Importers do not have to complete this section for operations outside the U.S.; however, you must report any processing or use activities after import. See the Instructions Manual. *Complete a separate section B for each type of processing, or use operation involving the new chemical substance*. If the same operation is performed at more than one site describe the typical operation common to these sites. Identify additional sites on a continuation sheet.

1(a). Operation Description -- To claim information in this section as confidential, bracket (e.g. {}) the specific information that you claim as confidential.

(1) -- Diagram the major unit operation steps and chemical conversions, including interim storage and transport containers (specify - e.g. 5 gallon pails, 55 gallon drums, rail cars, tank trucks, etc). On the diagram, identify by letter and briefly describe each worker activity.

(2) -- Either in the diagram or in the text field 1(b) below, provide the identity, the approximate weight (by kg/day or kg/batch, on an 100% new chemical substance basis), and entry point of all feedstocks (including reactants, solvents and catalysts, etc) and all products, recycle streams, and wastes. Include cleaning chemicals (note frequency if not used daily or per batch).

(3) -- Either in the diagram or in the text field 1(b) below, identify by number the points of release, including small or intermittent releases, to the environment of the new chemical substance.

(4) -- Please enter the # of sites (remember to identify the locations of these sites on a continuation sheet):

	Number of Sites	XXX	Confidential [X]

See Attachment (Sanitized Document: 6 Attach7_Process_by_Others...
)

1(b). (Optional) This space is for a text description to clarify the diagram above. Confidential [X]

XXX

Enter Attachment filename for Part II, Section B on the bottom of page 10a.	Sanitized Document: 6 Attach7_Process_by_Others... [X]

PMN Page 10a

2. Worker Exposure/Environmental Release

(1) -- From the diagram above, provide the letter for each worker activity. Complete 2-8 for each worker activity described.
(2) -- Estimate the number of workers exposed for all sites combined.
(4) -- Estimate the typical duration of exposure per worker in (a) hours per day and (b) days per year.
(6) -- Describe physical form of exposure and % new chemical substance (if in mixture), and any protective equipment and engineering controls, if any, used to protect workers.
(7) -- Estimate the percent of the new substance as formulated when packaged or used as a final product.
(9) -- From the process diagram above, enter the number of each release point. Complete 9-13 for each release point identified.
(10) -- Estimate the amount of the new substance released (a) directly to the environment or (b) into control technology to the environment (in kg/day or kg/batch).
(12) -- Describe media of release i.e. stack air, fugitive air (optional-see Instructions Manual), surface water, on-site or off-site land or incineration, POTW, or other (specify) and control technology, if any, that will be used to limit the release of the new substance to the environment.
(14) -- Identify byproducts which may result from the operation.
(3), (5), (8), (11), (13) and (15) -- Mark (X) this column if any of the proceeding entries are confidential business information (CBI).

Letter of Activity	# of Workers Exposed	CBI	Duration of Exposure		CBI	Protective Equip./Engineering Controls/Physical Form	% new substance	% in Formulation	CBI
(1)	(2)	(3)	(4a)	(4b)	(5)	(6)	(6)	(7)	(8)
XXX	XXX	X	XXX	XXX	X	XXX	XXX	XXX	X
XXX	XXX	X	XXX	XXX	X	XXX	XXX	XXX	X
XXX	XXX	X	XXX	XXX	X	XXX	XXX	XXX	X
XXX	XXX	X	XXX	XXX	X	XXX	XXX	XXX	X
XXX	XXX	X	XXX	XXX	X	XXX	XXX	XXX	X

Release Number	Amount of New Substance Released		CBI	Media of Release & Control Technology	CBI
(9)	(10a)	(10b)	(11)	(12)	(13)
XXX	XXX	XXX	X	XXX	X

Mark (X) this box if the data continues on the next page. ☐

(14) Byproducts: | **(15) CBI** ☐

Enter Attachment filename for Part II, Section B. ☐

OPTIONAL POLLUTION PREVENTION INFORMATION

To claim information in the following section as confidential, bracket (e.g. {}) the specific information that you claim as confidential.

In this section you may provide information not reported elsewhere in this form regarding your efforts to reduce or minimize potential risks associated with activities surrounding manufacturing, processing, use and disposal of the PMN substance. Please include new information pertinent to pollution prevention, including source reduction, recycling activities and safer processes or products available due to the new chemical substance. Source reduction includes the reduction in the amount or toxicity of chemical wastes by technological modification, process and procedure modification, product reformulation, and/or raw materials substitution. Recycling refers to the reclamation of useful chemical components from wastes that would otherwise be treated or released as air emissions or water discharges, or land disposal. Quantitative or qualitative descriptions of pollution prevention, source reduction and recycling should emphasize potential risk reduction in addition to compliance with existing regulatory requirements. The EPA is interested in the information to assess overall net reductions in toxicity or environmental releases and exposures, not the shifting of risks to other media (e.g., air to water) or nonenvironmental areas (e.g., occupational or consumer exposure). To the extent known, information about the technology being replaced will assist EPA in its relative risk determination. In addition, information on the relative cost or performance characteristics of the PMN substance to potential alternatives may be provided.

Describe the expected net benefits, such as

(1) an overall reduction in risk to human health or the environment;
(2) a reduction in the generation of waste materials through recycling, source reduction or other means;
(3) a reduction in the use of hazardous starting materials, reagents, or feedstocks;
(4) a reduction in potential toxicity, human exposure and/or environmental release; or
(5) the extent to which the new chemical substance may be a substitute for an existing substance that poses a greater overall risk to human health or the environment.

Information provided in this section will be taken into consideration during the review of this substance. See PMN Instructions Manual and Pollution Prevention Guidance manual for guidance and examples.

Enter Attachment filename for Pollution Prevention Page 11.		☐

Part III -- LIST OF ATTACHMENTS

Attach continuation sheets for sections of the form, test data and other data (including physical/chemical properties and structure/activity information), and optional information after this page. Clearly identify the attachment and the section of the form to which it relates, if appropriate. Number consecutively the pages of any paper attachments. In the Number of Pages column below, enter the inclusive page numbers of each attachment for paper submissions or enter the total number of pages for each attachment for electronic submissions. Electronic attachments can be identified by filename.
Mark (X) the "Confidential" box next to any attachment name or filename you claim as confidential. Read the Instructions Manual for guidance on how to claim any information in an attachment as confidential. You must include with the sanitized copy of the notice form a sanitized version of any attachment in which you claim information as confidential.

#	Attachment Name	Attachment Filename	Number of Pages	Associated PMN Section Number	CBI
1	Safety Data Sheet	Attach3_SDS_sanitized.pdf	4	Hazard Information Section (Chemical 546952)	
2	Chemical Structure Diagram	Attach2_Structure_sanitized.pdf	1	Polymers Identification Substances Chemical Structure Diagram	
3	IES Report	Attach1_IES_sanitized.pdf	2	Polymers Identification Substances ID Method (Chemical 546952)	
4	GPC report	Attach5_GPC_sanitized.pdf	11	Monomers (Chemical 546952)	
5	Cover Letter of Explanation with Revised Process Flow Sheet	Cover Letter with revised Attach 4 - sanitized.pdf	3	Submitter Controlled Operations (Operation 1)	
6	Process by Others	Attach7_Process_by_Others_sanitized.pdf	1	Industrial Sites Controlled By Others (Operation 1)	
7	Mutagenicity Test by using microorganisms	Attach6_Ames_sanitized.pdf	19	Additional Attachments	

Mark (X) this box if the data continues on the next page. ☐

PMN Page 13

PHYSICAL AND CHEMICAL PROPERTIES WORKSHEET

The information on this page refers to chemical number(s): [X] 1 [ ] 2 [ ] 3 [ ] 4 [ ] 5 [ ] 6

To assist EPA's review of physical and chemical properties data, please complete the following worksheet for data you provide and include it in the notice. Identify the property measured, the value of the property, the units in which the property is measured (as necessary), and whether or not the property is claimed as confidential. Give the attachment number (found on page 12) in column (b). The physical state of the neat substance should be provided. These measured properties should be for the neat (100% pure) chemical substance. Properties that are measured for mixtures or formulations should be so noted (% PMN substance in __). You are not required to submit this worksheet; however, EPA strongly recommends that you do so, as it will simplify the review and ensure that confidential information is properly protected. You should submit this worksheet as a supplement to your submission of test data. This worksheet is not a substitute for submission of test data.

Property (a)		Unit	Mark X if Provided	Attachment Number (b)	Value (c)			Measured or Estimate (M or E)	CBI Mark (X) (d)
					(solid)	(liquid)	(gas)		
Physical state of neat substance			[X]		[X]	[ ]	[ ]	Measured	
Vapor Pressure @ Temperature		°C	[ ]				Torr		
Density/relative density			[X]		1.7 - 1.8		g/cm3	Measured	
Solubility			[X]		1000		g/L	Estimate	
@ Temperature	25	°C							
Solvent	acetone								
Solubility in Water @ Temperature	25	°C	[X]		0		g/L	Measured	
Melting Temperature			[ ]				°C		
Boiling / Sublimation temperature @		Torr	[ ]				°C		
Spectra			[ ]						
Dissociation constant			[ ]						
Octanol / water partition coefficient			[ ]						
Henry's Law constant			[ ]						
Volatilization from water			[ ]						
Volatilization from soil			[ ]						
pH@ concentration			[ ]						
Flammability			[ ]						
Explodability			[ ]						
Adsorption / Coefficient			[ ]						
Particle Size Distribution			[ ]						
Other – Specify			[ ]						

October 19, 2018

Contains TSCA CBI

Geraldine Hilton, Program Manager,
Chemical Control Division, OPPT
U.S. Environmental Protection Agency (7405M)
Wm. Jefferson Clinton Building
1200 Pennsylvania Ave. NW
Washington, D.C. 20460

Re: Revised Attachment for PMN P-17-0400

Dear Ms. Hilton,

[CBI

]

Please contact me when you have received this submission. I look forward to hearing from you.

Sincerely,

[CBI]

[CBI]

Process Flow Sheet

CBI SUBSTANTIATION

For PMNs, SNUNs, TMEAs, LVEs, and LOREXs filings

Use of this form is recommended, but not required.

This Document Contains CBI: Yes☐ NO☒

Technical Contact: CBI

Technical Contact Phone Number: CBI | **Submission number (if known):** Click here.

Submitting Company Name: CBI

Information element(s) claimed as CBI: Please identify the information element(s) that you are substantiating from the list below.

You are responsible for substantiating each information element claimed as CBI (unless that item is exempt from the substantiation requirement—see endnote 1). Any information element that is not specifically identified as subject to a confidentiality claim and substantiated as such in your response to this letter, it shall be determined that you have waived your CBI claim. If a single substantiation response applies for all information claimed as CBI, you should indicate this in your substantiation response. If different substantiation responses are necessary to support CBI claims for different information types, you should provide separate substantiation responses for each information type, clearly identifying the information for which each substantiation applies in the free text boxes (e.g. Question B) or in the additional information box at the end of this form.

☒ Signature and Date of Authorized Official (Page 2)	☒ Production Volume (Part I Section C.1)*
☐ Signature and Date of Agent (Page 2)	☒ Category of Use (Part I Section C.2.a.1)*
☒ Person Submitting Notice (Part I Section A.1.a)	☐ Use Production (Part I Section C.2.a.4)*
☐ Agent (Part I Section A.1.b)	☒ % in Formulation (Part I Section C.2.a.6)*
☐ Joint Submitter (Part I Section A.1.c)	☒ % of Substance Expected Per Use (Part I Section C.2.a.8)*
☒ Technical Contact (Part I Section A.2)	☐ Site Identity (Part II Section A.1.a)
☐ Prenotice Communication (PC) (Part I Section A.3)	☐ Number of Sites (Part II Section A.1.a)
☐ Previously Submitted Exemption Application (Part I Section A.4)	☐ Site Operations (Part II Section A.1.b)
☐ Previously Submitted Bona Fide (Part I Section A.5)	☐ Amount and Duration (Part II Section A.1.c)*
☐ Chemical Class (Part I Section B.1.a)	☐ Process Description (Part II Section A.1.d)*
☐ Chemical Name (Part I Section B.1.b)**	☐ Worker Activity (Part II Section A.2.1)
☐ Molecular Formula (Part I Section B.1.d)**	☐ Physical Form(s) & % New Substance (Part II Section A.2.5)
☐ Chemical Structure Diagram for Class I (Part I Section B.1.e)**	☐ # of Workers Exposed (Part II Section A.2.8)
☐ Precursor Substances Class II (Part I Section B.1.e.1)*	☐ Maximum Duration (Part II Section A.2.10-11)
☐ Reaction or Process for Class II (Part I Section B.1.e.2)*	☐ Release Number and Amount of New Substance Released (Part II Section A.3.1-2)
☐ Range of Composition and Typical Composition for Class II (Part I Section B.1.e.3)*	☐ Medium of Release and Control Technology and Efficiency (Part II Section A.3.4-5)
☒ Polymer Information (Part I Section B.2.a)**	☐ Destinations of Releases to Water (Part II Section A.3.7)
☒ Monomer or Other Reactant Specific Chemical Name (Part I Section B.2.b.1)*	☒ Operation Description (Part II Section B.1)*
☒ Monomer or Other Reactant Specific Chemical Name Typical Composition / Include in Identity (Part I Section B.2.b.3-4)	☒ Letter of Activity and # of Workers Exposed (Part II Section B.2.1-2)

☒ Monomer or Other Reactant Specific Chemical Name Max Residual (Part I Section B.2.b.6)	☒ Duration of Exposure (Part II Section B.2.4)
☒ Current Chemical Abstracts (CA) Name and Number for Polymer (Part I Section B.2.d)**	☒ Protective Equipment/Engineering Controls/Physical Form/ % New Substance/% in Formulation (Part II Section B.2.6-7)
☒ Chemical Structure Diagram (Part I Section B.2.e)**	☒ Release Number and Amount of New Substance Released (Part II Section B.2.9-10)
☐ Impurities (Part I Section B.3)	☐ Media of Release & Control Technology (Part II Section B.2.12)
☐ Synonyms (Part I Section B.4)	☐ Byproducts (Part II Section B.2.14)
☒ Trade Identification (Part I Section B.5)	☐ Pollution Prevention Information (PMN page 11, form page 16)
☐ Byproducts (Part I Section B.7)	☐ Physical and Chemical Properties Worksheet (PMN page 13, Form page 18)***

☒**Other information elements claimed as CBI** (Please list any other CBI claim or any TSCA Section 14(c)(2) assertion not listed above):
Attachment 1 (IES),
Attachment 2 (Structure),
Attachment 3 (SDS),
Attachment 4 (Process),
Attachment 5 (GPC),
Attachment 6 (Ames),
Attachment 7 (Process by Others)
This CBI Substantiation Form and our Responses also are CBI

I. REQUIRED FOR ANY IDENTIFIED CBI CLAIM

A. Do you believe that any information element claimed as CBI is exempt from substantiation pursuant to TSCA section 14(c)(2)[1]?

☑ Yes
☐ No

If you answered yes, you must identify the specific information element(s), provide the specific exemption(s) and answer no further questions. For any information element that is not exempt, please respond to all of the questions below.

If the Agency disagrees with this assertion, you may be asked to provide additional information to support your claim.

The Company agrees with EPA that the information elements marked with a "*" or a "**" in the above section "The information element(s) claimed as CBI" are exempt from CBI substantiation under TSCA Section 14(c)(2), including the Company has not yet offered the PMN substance for commercial distribution. The Company has clearly marked these elements as CBI and has redacted in the sanitized copy such information where it appears in the PMN and the attachments listed in Part III.1 - 6.

In addition, the Company has claimed as CBI the information in Part I Section B.2.b 3, 4, and 5, Part II.B.2, and similar information in the attachments. These claims do not require any substantiation, including because this specific information pertains to either: (1) "the processed used in manufacturing or processing of a chemical substance, mixture, or article," or (2) "the specific chemical identity of the chemical substance, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify the specific chemical substance" and the Company has not yet offered the PMN substance

for commercial distribution. 15 U.S.C. § 2613(c)(2)(A) & (G). The Company has clearly marked these elements as CBI and has redacted in the sanitized copy such information where it appears in the PMN and the attachments listed in Part III.1 - 6.

Finally, the Company also has claimed as CBI information in the PMN and the attachments that directly or indirectly discloses the Company's identity (e.g., company name; employees' names; identity of sites where operations occur; trade identification) (hereinafter, collectively referred to as "Company Identifying CBI"). The Company is providing below upfront substantiation for these claims.

To be clear, consistent with EPA's instructions above, the Company is not providing responses to I.B - G below for any CBI claims other than the Companying Identifying CBI because such other CBI claims are exempt from upfront substantiation. *See* Instructions to I.A ("*If you answered yes, you must identify the specific information element(s), provide the specific exemption(s)* ***and answer no further questions***. ***For any information element that is not exempt, please respond to all of the questions below.***") (emphasis added).

B. Will disclosure of any information element claimed as CBI likely result in substantial harm to your business's competitive position?

☑ Yes
☐ No

(If you answered yes, please describe with specificity the substantial harmful effects that would result to your competitive position if the CBI information element is made available to the public.)

If you are claiming multiple information elements, please make sure to provide information for EACH element you identified above. If a single substantiation response applies for all information claimed as CBI, you should indicate this in your substantiation response.

The Company is a leading innovator in the {CBI} market, which is a small and competitive market. The disclosure of the Company Identifying CBI would alert the Company's competitors that the Company is planning to bring another product to market and potentially spur a competitor to try to beat the Company to market. Disclosure of the names of our employees, trade name of the chemical substance, and facilities is tantamount to disclosure of the Company's name.

The Company has invested millions of dollars in developing the chemical substance and the public disclosure of the Company Identifying CBI threatens to undermine these investments. The harmful effects of disclosure are magnified by the fact that the Company has not yet offered the chemical substance into commerce and, to the submitter's knowledge, the Company's future plans for doing so are not public knowledge.

C. To the extent your business has disclosed any information to others (both internally and externally), what precautions has your business taken? Please identify the measures or internal controls your business has taken to protect the information claimed as confidential.

1. Non-disclosure agreement required prior to access. ☑ Yes ☐ No
2. Access is limited to individuals with a need-to-know. ☑ Yes ☐ No
3. Information is physically secured (e.g. locked in room or cabinet) or electronically secured (encrypted, password protected, etc.). ☑ Yes ☐ No
4. Other internal control measure(s). *(If yes please explain below.)* ☐ Yes ☐ No

TSCA Section 14(c)(1)(B)(i) requires the Company to include a statement with its CBI claims that it has "taken reasonable measures to protect the confidentiality of the information." The specific measures listed in C.1 - 3 are not required under Section 14(c)(1)(B)(i). The Company therefore objects to this question to the extent it suggests that the Company had to have followed the processes

specified in C.1 - 3 in order to demonstrate that it has satisfied TSCA Section 14(c)(1)(B)(i). Subject to and without waiving the foregoing, the Company responds to this question as follows: The Company has not disclosed to the public that it plans to begin manufacturing or importing the chemical substance. Such information is also controlled within the Company and limited to a small subset of employees and third parties subject to a non-disclosure agreement.

D. Does any of the information claimed as confidential appear in any public documents, including (but not limited to) safety data sheet, advertising or promotional material, professional or trade publication, or any other media or publications available to the general public? *(If you answered yes, please explain why the information should be treated as confidential.)*	☑ Yes ☐ No
The information appears on the SDS, but the SDS is only provided to R&D customers under a non-disclosure agreement.	
E. Does any of the information you are claiming as CBI contain (a) trade secret(s)[2]? *(If you answered yes, please explain the reason for your belief and attach copies of those pages containing such information with brackets around the text that you claim to be (a) trade secret(s).)*	☐ Yes ☑ No
The Company has claimed certain information which is trade secret (e.g., specific chemical identity) to be CBI. However, pursuant to TSCA Section 14(c)(2) and as explained in the Company's response to Questions I.A above, substantiation is not required at this time for such CBI claims containing trade secrets.	
F. If you assert a claim of confidentiality that is less than 10 years (see TSCA section 14(e)(1)(B)[3]), then please indicate the number of years (between 1-10 years) or specific date of which the claim is withdrawn[4]?	
Not applicable	
G. Has the EPA, another federal agency, or court made any confidentiality determination regarding information associated with this substance? *(If you answered yes, please explain the outcome of that determination and provide a copy of the previous confidentiality determination or any other information that will assist in identifying the prior determination.)*	☐ Yes ☑ No
Click or tap here to enter text.	

II. REQUIRED ONLY FOR CHEMICAL IDENTITY CBI CLAIMS	
A. Are you claiming a specific chemical identity as CBI? *(If you answered yes, please respond to questions below.* *If you answered no, please leave all questions below blank.)* Pursuant to TSCA Section 14(c)(2)(G), substantiation of specific chemical identity is not required "[pr]ior to the date on which a chemical substance is first offered for commercial distribution." To the Company's knowledge, the chemical substance at issue in the Company's PMN has not been offered for commercial distribution. Accordingly, the Company is exempt from—and has not answered the questions—in Part II.	☐ Yes ☐ No
B. Is the chemical substance (or mixture) on the confidential portion of TSCA Inventory?	☐ Yes

	☐ No ☐ Don't know
C. Has the chemical substance (or mixture) been offered for commercial distribution? *(If you answered yes, please explain why the information should be treated as confidential.)*	☐ Yes ☐ No
Click or tap here to enter text.	
D. Is the chemical substance known to be in US commerce? *(If you answered yes, please explain why the information should be treated as confidential.)*	☐ Yes ☐ No
Click or tap here to enter text.	
E. Would disclosure of the specific chemical name release confidential process information? *(If you answered yes, please explain what process information would be released.)*	☐ Yes ☐ No
Click or tap here to enter text.	
F. In the case of a mixture, would disclosure of the chemical name disclose a portion of the mixture comprised by any of the chemical substances in the mixture? *(If you answered yes, please explain what information would be released.)*	☐ Yes ☐ No
Click or tap here to enter text.	
Additional comments:	
As noted in the Company's response in II.A., above, the Company is asserting a CBI claim for the specific chemical identity and related information that might reveal that identity. The Company understands that no substantiation for such claims is required at this time because Section 14(c)(2) exempts such claims during the period prior to submittal of a Notice of Commencement of Manufacture for the substance.	

III. SUBSTANTIATION CERTIFICATION	
Do you wish to claim this substantiation as CBI? *TSCA section 14(c) requires that persons asserting a CBI claim shall certify to the validity of the claims. By the marking of a yes, you are certifying to the truth of the below statements.*	☑ Yes ☐ No

I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate.

I further certify that, pursuant to 15 U.S.C. § 2613(c), for all claims for confidentiality made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that

(i) My company has taken reasonable measures to protect the confidentiality of the information;

(ii) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;
(iii) I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of my company; and
(iv) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. § 1001.

---

[*] EPA believes this information element to be exempt from substantiation for this activity.
[**] EPA believes this information element to be exempt from substantiation for this activity (this exemption only applies prior to the date on which a chemical substance is first offered for commercial distribution).
[***] EPA believes Spectra claims to be exempt from substantiation for this activity (this exemption only applies prior to the date on which a chemical substance is first offered for commercial distribution).

[1] **"TSCA Section 14(c)(2) states:**
Information generally not subject to substantiation requirements
Subject to subsection (f), the following information shall not be subject to substantiation requirements under paragraph (3):
(A) Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article.
(B) Marketing and sales information.
(C) Information identifying a supplier or customer.
(D) In the case of a mixture, details of the full composition of the mixture and the respective percentages of constituents.
(E) Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or article.
(F) Specific production or import volumes of the manufacturer or processor.
(G) Prior to the date on which a chemical substance is first offered for commercial distribution, the specific chemical identity of the chemical substance, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify the specific chemical substance, if the specific chemical identity was claimed as confidential at the time it was submitted in a notice under section 2604 of this title.

[2] **"Trade secret"** is defined as "a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C. Cir. 1983).

[3] **"TSCA section 14(e)(1)(B) States"**
(B) in the case of information other than information described in subsection (c)(2)—
(i) for a period of 10 years from the date on which the person asserts the claim with respect to the information submitted to the Administrator; or
(ii) if applicable before the expiration of such 10-year period, until such time as—
(I) the person that asserted the claim notifies the Administrator that the person is withdrawing the claim, in which case the information shall not be protected from disclosure under this section; or
(II) the Administrator becomes aware that the information does not qualify for protection from disclosure under this section, in which case the Administrator shall take any actions required under subsections (f) and (g).

[4] Information with withdrawn CBI claims may be made available to the public without further notice.

Attachment 1

A division of the American Chemical Society

InventoryExpertService

Phone: 800-631-1884, 614-447-3870
Fax: 614-447-3747
E-mail: answers@cas.org
Web: www.cas.org/products/other-cas-products/client-services/

INVENTORY EXPERT SERVICE REPORT

IES Order Number:

Registry Number:

CA Index Name:

Please print the above CA Index Name on the appropriate page of your PMN.

[X] If this box is checked, CAS has made correction(s) marked in red to your IES order. Please make the same corrections to your PMN before submitting it to the EPA.

Monomer or other reactant specific chemical name	CAS	Typical composition	Include in identity	Max residual

Please include when submitting to the EPA.

CONFIDENTIAL

Chemical structure diagram

Material Safety Data Sheet

Issued Apr-22-2014 Revised Feb-27-2017

Section1: Identification of the substance and manufacturer

Trade name **[R&D USE ONLY]**
Synonym Base Resistant fluoroelastomer
Iodine modified fluoroelastomer

Application

Company identification
Manufacturer

Supplier in EU

Supplier in US

Emergency Telephone Contacts

Section 2: Hazard identification

Skin Burns from contact with molten material. Signs/symptoms may include burning pain, red and swollen skin, and blisters.

Danger! Vapors and fumes liberated during hot processing with this material may cause flu-like symptoms (chills, fever, sore throat) that may not occur until several hours after exposure and typically pass within about 36 to 48 hours.

HAZARDOUS DECOMPOSITION PRODUCTS:

Carbon Monoxide and Carbon Dioxide, Hydrogen Fluoride (HF), Carbonyl Fluoride (COF_2), Perfluoroisobutylene (PFIB) Toxic Vapors, Gases or Particulates.

Section 3: Composition / information on ingredients

Component	CAS No.	mass %	Symbol	R-pharases
		>99.0%	n.ap	n.ap

Section 4: First aid measures

Inhalation	If decomposed gas is inhaled, fresh air, rest. Refer for medical attention.
Skin Contact	The compound is not likely to be hazardous, but cleansing the skin after use. If skin contact with hot material occurs: DO NOT ATTEMPT TO REMOVE MOLTEN MATERIAL. Immediately flush affected area with plenty of cold water and cover with a clean dressing. Have burn treated by a physician.
Eye Contact	Eye contact is not considered a potential route of exposure. If eye contact with hot material occurs, first rinse with plenty of water for 15 minutes (remove contact lenses if easily possible), then the eye should be treated by a physician.
Ingestion	Ingestion is not considered a potential route of exposure.

SECTION 5: Fire-fighting measures

General Information	Non-flammable. Wear self-contained breathing apparatus (SCBA) and full protective gear. Use water spray to cool fire exposed containers. During a fire, irritating and highly toxic gases may be generated by thermal decomposition or combustion.
Extinguishing Media	Water, powder, alcohol-resistant foam, carbon dioxide.
Combustion products	These products are harmful CO, CO_2, halogenated compounds. WARNING: TOXIC FLUORINE COMPOUNDS EVOLVED IN FIRE.

SECTION 6: Accidental release measures

Spills/leaks is not considered.

SECTION 7: Handling and storage

HANDLING

Wear suitable protective clothing (see section 8)

Exposure to toxic gases through inhalation can occur if smoking tobacco becomes contaminated by this material. Therefore, do not smoke in the work areas and wash hands and face after handling in order to avoid transfer of the material onto smoking tobacco.

STORAGE

Keep away from heat, steam or sunlight.

Keep containers tightly closed when not in use.

SECTION 8: Exposure controls / personal protection

Engineering Controls

Use local exhaust ventilation facilities when molding or curing.

Use ventilation to keep exposure to airborne contaminants below the exposure limit.

Exposure Limits

HF	TLV: (as F): 3ppm; (ceiling values)(ACGIH 1999) MAK: 3ppm; 2.5mg/m3, BAT 7mg/g creatinine (1999) MAK as STEL: 6ppm, 5mg/m3 (1999)
COF_2	TLV: 2ppm; 5.4mg/m3 (as TWA); 5ppm; 13mg/m3 (as STEL) (ACGIH 1997)
PFIB	TLV: 0.01ppm; 0.082 mg/m3 (ceiling values) (ACGIH 1993-1994).
CH_3I	TLV: 2 ppm; 12 mg/m³ as TWA (skin) (ACGIH 1998).

Personal Protective Equipment

Wear safety glasses with side shields.

Wear appropriate gloves, when handling this material to prevent thermal burns.

Wear protective clothing and boots as required.

Maximum safe processing temperature is 200℃.

A NIOSH approved air purifying organic vapor/acid gas cartridge respirator with P100 particulate pre-filters is recommended when processing this material.

SECTION 9: Physical and chemical properties

Appearance	White to clear sheet
Odor	No
Boiling point	N.ap
Melting point	N.ap
Specific gravity	1.71 (H_2O=1 at 20 C)
Solubility in water	Insoluble
Solubility	Soluble in ketones, esters, ethers
Flash Point	None
Autoignition Temp	No data
Explosion Limits	Lower: none Upper: none

SECTION 10: Stability and reactivity

Chemical Stability	Stable under normal temperatures and pressures. When heated above 200 C, a very small quantity of hydrogen fluoride (HF), carbonyl fluoride(COF_2) Perfluoroisobutylene (PFIB) is generated. Further the higher temperature(above 300 C), the larger it will increase.
Conditions to Avoid	Ignition sources, excess heat.
Incompatibility (materials to avoid)	Finely divided metallic powder or filler, such as aluminum and magnesium. Contact with oxidizer, such as F_2 and Cl_3F, can cause fire or explosion.
Hazardous Decomposition Products	Carbon monoxide, carbon dioxide, HF, COF_2 and PFIB and CH_3I.
Polymerization	Will not occur.

SECTION 11: Toxicological information

When compound is handled in heated for a long time, a very small quantity of hydrogen fluoride (HF), carbonyl fluoride(COF_2) Perfluoroisobutylene (PFIB) is generated. Further the higher temperature, the larger it will increase.
This polymer contains iodide, so organic substance like CH_3I may be generated.

(as HF or COF_2)
Burning sensation. Cough. Dizziness. Headache. Laboured breathing. Nausea. Shortness of breath. Sore throat. Vomiting. Symptoms may be delayed.
Inhalation of this gas or vapour may cause lung oedema.

(as PFIB)
The substance irritates the respiratory tract. Inhalation of this gas may cause lung oedema. Exposure may result in death. The effects may be delayed. Medical observation is indicated.

(as CH_3I)
The substance irritates the eyes, the skin and the respiratory tract. Inhalation of may cause lung oedema. The substance may cause effects on the central nervous system and kidneys. Exposure at high levels may result in unconsciousness. The effects may be delayed. Medical observation is indicated.

SECTION 12: Ecological information

Exotoxicity	Exotoxicity is expected to be low based on the near zero water solubility of the polymer. Material is considered inert and not expected to be biodegradable or toxic.

SECTION 13: Disposal considerations

Dispose of in compliance with Federal, state and local government regulations.
Usually considered an inert packaging material that can be recycled or landfilled.
Incineration is not a preferred disposal method because of the possible formation of hydrogen fluoride.

SECTION 14: Transport information

Hazard Class	Not regulated.
UN Number	Not applicable, none assigned.

SECTION 15: Regulatory information

No information

SECTION 16: Other information

This product is not designed, manufactured, or intended for medical uses, including implantation to the body or other applications in direct contact with body fluids or tissues.
Do not use for non-industrial applications.

The information in this Material Safety Data Sheet (MSDS) is believed to be correct as of the date issued. The information dose not relate to use in combination with any other material or in any process.

S413635

Measurement of molecular weight of

[Abstract]

The measurement of the molecular weight (MW) distribution to estimate the average molecular weight and the content of components with MW less than 1000 and 500 of the test sample " " was carried out using GPC. Characteristics of the sample are summarized in Table A. Molecular weight distribution curves are shown in Fig.A.

The content of the components with MW less than 1000 and 500 can be estimated 0.06% and 0.00%, respectively.

Table A Characteristics of the sample

Sample	Number average molecular weight (*Mn*) *	Weight average molecular weight (*Mw*) *	Z average molecular weight (*Mz*) *	Peak top molecular weight (*Mp*) *	Polydispersity		Content of Component MW < 1000	Content of Component MW < 500
					Mw/*Mn*	*Mz*/*Mw*		
	81400	232000	529000	141000	2.85	2.28	0.06%	0.00%

*relative values of polystyrene standards

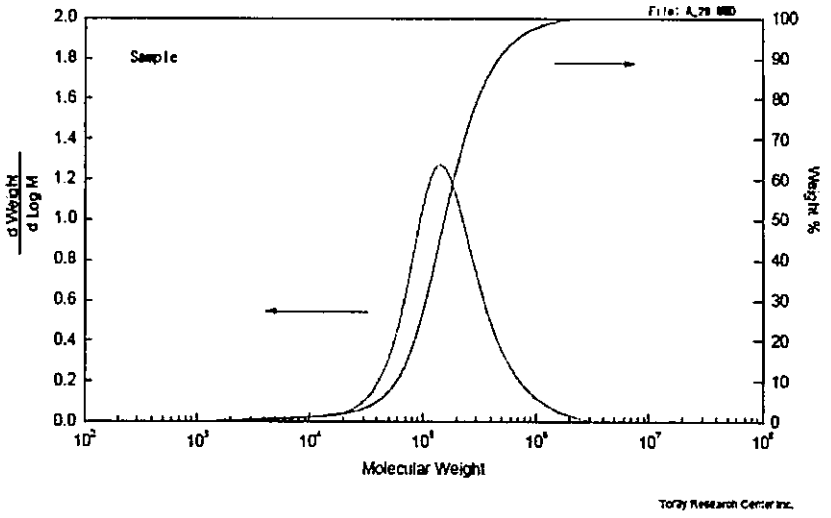

Fig.A Molecular Weight Distribution Curves

Contents

Report : 4 pages
Figure : 4 pages
Table : 3 pages

Person in charge

Manager : Hideaki Takahashi
Research Associate : Kazutomo Akasaka
TEL: +81-77-533-8603, FAX: +81-77-533-8637
Address : 3-3-7, Sonoyama, Otsu, Shiga 520-8567

1. Objective

To estimate the average molecular weight and the content of the components with MW less than 1000 and 500

2. Sample

Chemical Name :

CAS No. :

3. Experimental

3.1 Method

Gel permeation chromagraphy (GPC)

3.2 Principle

GPC (gel permeation chromatography) is one of the liquid chromatography to separate polymer samples according to the difference in their molecular size. The molecular weight distribution is measured using GPC.

3.3 Experimental conditions

Apparatus	: Gel permeation chromatography
Detector	: Defferential refractive index detector RI-8020 (TOSOH)
Column	: TSKgel $GMH_{XL}(2)$ (TOSOH)
Mobile phase	: Tetrahydrofuran
Flow rate	: 1.0 mL/min
Temperature	: 23 °C
Sample concentration	: 0.20% (w/v)
Solubility	: Soluble
Filtration	: Millex-LH, 0.45 μm (Millipore)
Injection volume	: 0.200 mL
Polymer standards	: Polystyrene (TOSOH)
Data processing	: GPC data processing system (TRC)

The method of the present study is equivalent to OECD TG 118.

4. Results

The GPC curve of the sample is shown in Fig.1. The signals of the eluted sample are detected from about 12 to 21 minute. The peaks detected after about 21 minute are attributable to the solvent-composition-change, solvent-impurity, residual monomer and/or the system peak.

The GPC curves of the standard polystyrene samples are shown in Fig.2.

Fig.4 shows the molecular weight distribution curves calculated based on the calibration curve[*1] shown in Fig.3. The average molecular weight is summarized in Table A. In this report, the molecular weight is calculated as the relative value of the standard polystyrene samples.

The MWD data is listed in Table 1. The content of the components with the molecular weight less than 1000 and 500 can be estimated 0.06% and 0.00%, respectively.

[*1] The calibration curve (third-order approximation) can be obtained from the relationship between the molecular weight and elution time of the standard polystyrene.

This work was carried out by Research Associate Kazutomo Akasaka and Manager Hideaki Takahashi at 1st Materials Characterization laboratory, Toray Research Center, Inc.

Manager : Hideaki Takahashi

Signature : Hideaki Takahashi Date : Feb. 21, 2017

Study Director : Kazutomo Akasaka

Signature : Kazutomo Akasaka Date : Feb. 21, 2017

Fig . 1 Gel Permeation Chromatogram

Sample	:	Solvent	: THF
Concentration	: 0.2 %	Flow Rate	: 1.0 mL/min
Injection Volume	: 0.200 mL	Detector	: RI-8020 (32x)
Apparatus	: GPC-MALS(1)	Temperature	: 23.0℃
Column	: TSKgel GMHXL(2)	Operator	: Yoshida
		Date	: 2015/06/30

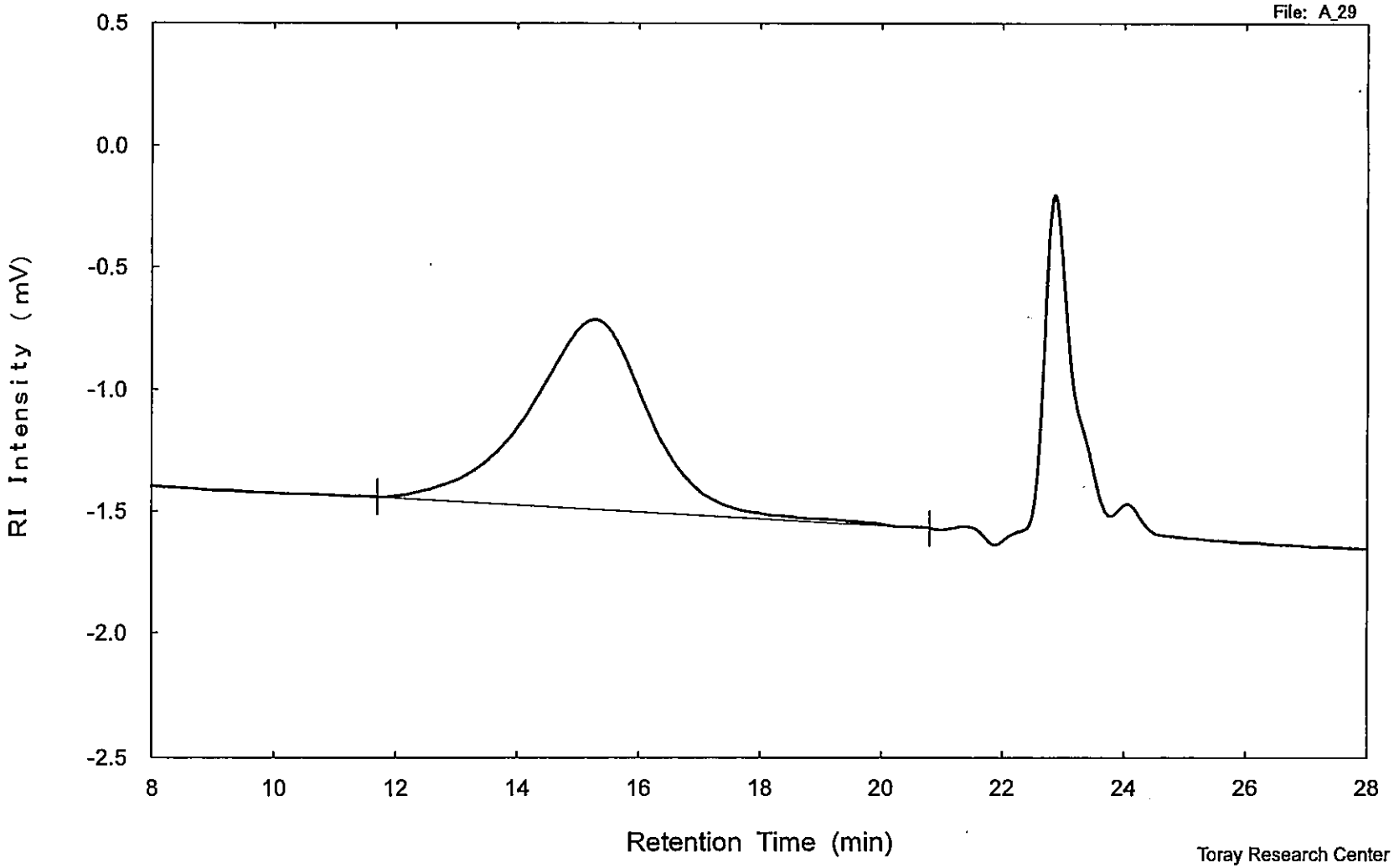

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Fig . 2 Gel Permeation Chromatogram

Concentration	: -	Solvent	: THF
Injection Volume	: 0.200 mL	Flow Rate	: 1.0 mL/min
Apparatus	: GPC-MALS(1)	Detector	: RI-8020 (32x)
Column	: TSKgel GMHXL(2)	Temperature	: 23.0℃
		Operator	: Yoshida
		Date	: 2015/06/30

File: A_25 A_26 A_27

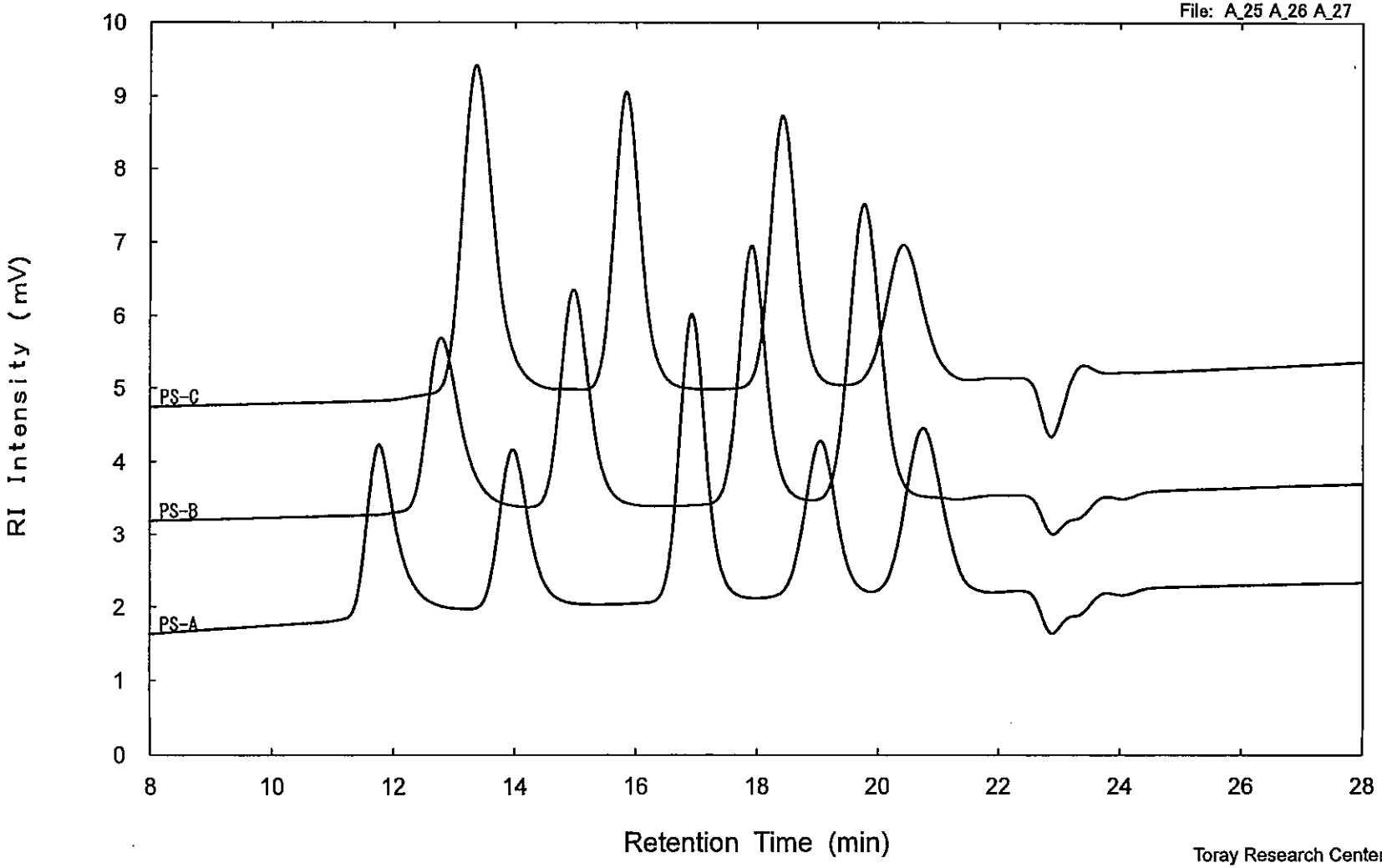

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Fig . 3 Calibration Curve

Sample	: Polystyrene	Detector	: RI-8020 (32x)
Apparatus	: GPC-MALS(1)	Temperature	: 23.0℃
Column	: TSKgel GMHXL(2)	Operator	: Yoshida
Solvent	: THF	Date	: 2015/06/30
Flow Rate	: 1.0 mL/min		

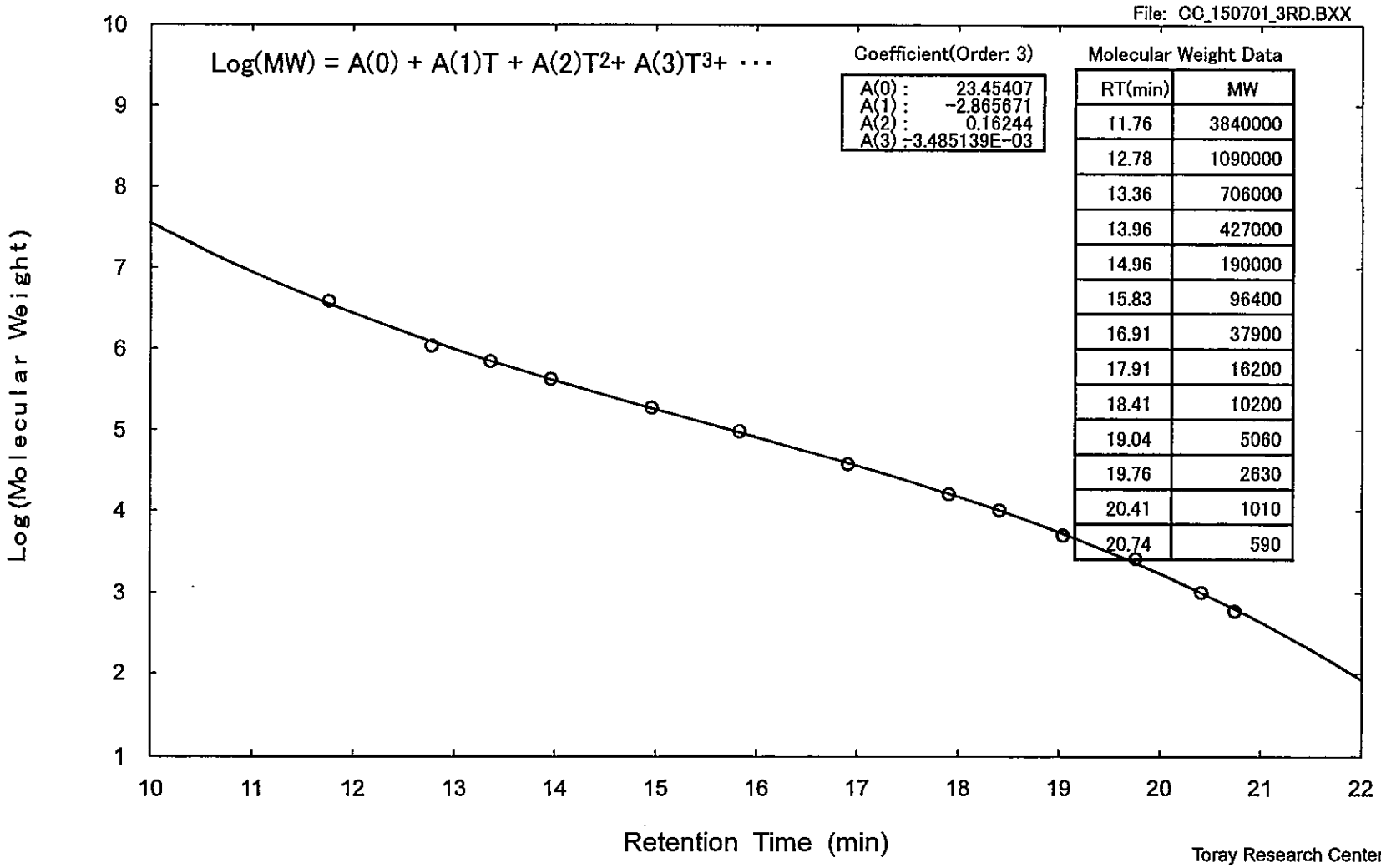

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Fig.4 Molecular Weight Distribution Curve

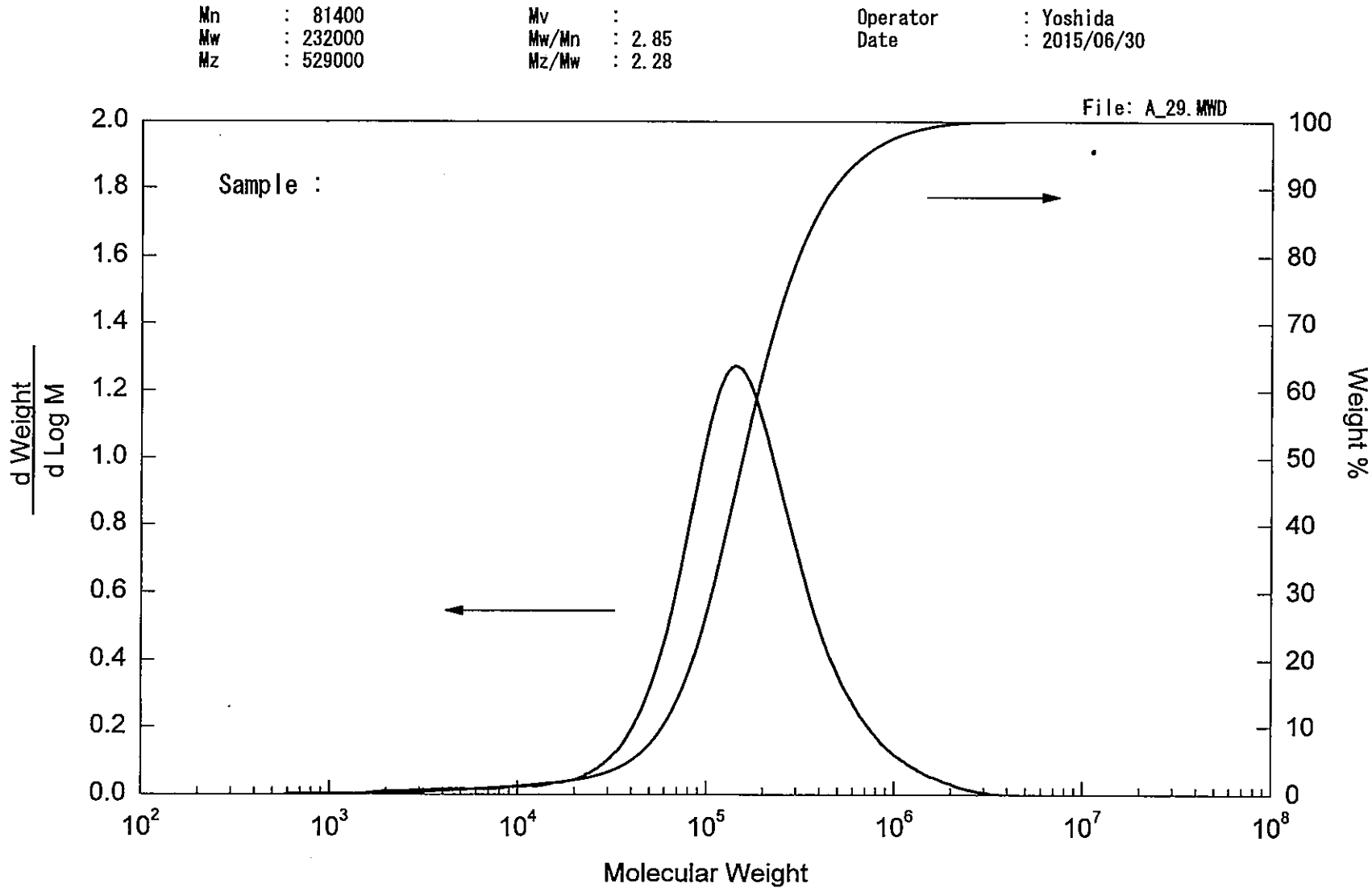

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Table 1 Molecular Weight Data

S413635

Sample :
File : a_29.MWD
Area : 107.16 mV・sec
Operator: Yoshida
Date : 2015/6/30

Mn : 81400
Mw : 232000
Mz : 529000
Mv :
Mw/Mn: 2.85
Mz/Mw: 2.28

Retention Time (min)	Molecular Weight	Intensity (mV)	d(Weight) / d Log(MW)	Weight %
11.71	3752786	0.000	0.000	100.00
11.75	3613343	0.000	0.000	100.00
11.78	3479790	0.001	0.002	100.00
11.81	3351843	0.001	0.001	100.00
11.85	3229244	0.002	0.002	99.99
11.88	3111746	0.004	0.005	99.99
11.91	2999106	0.005	0.006	99.98
11.95	2891107	0.006	0.007	99.97
11.98	2787530	0.007	0.008	99.96
12.01	2688177	0.008	0.010	99.94
12.05	2592851	0.010	0.012	99.92
12.08	2501374	0.011	0.014	99.90
12.11	2413569	0.013	0.016	99.88
12.15	2329275	0.014	0.018	99.85
12.18	2248330	0.017	0.020	99.82
12.21	2170587	0.019	0.023	99.79
12.25	2095907	0.021	0.026	99.75
12.28	2024151	0.024	0.030	99.71
12.31	1955193	0.026	0.032	99.66
12.35	1888909	0.029	0.036	99.61
12.38	1825185	0.030	0.038	99.55
12.41	1763907	0.033	0.041	99.49
12.45	1704972	0.036	0.046	99.43
12.48	1648278	0.037	0.048	99.36
12.51	1593729	0.040	0.051	99.28
12.54	1541236	0.042	0.054	99.21
12.58	1490709	0.045	0.058	99.12
12.61	1442068	0.048	0.062	99.04
12.64	1395230	0.051	0.067	98.94
12.68	1350124	0.053	0.070	98.84
12.71	1306675	0.058	0.076	98.74
12.74	1264816	0.060	0.079	98.63
12.78	1224479	0.063	0.084	98.51
12.81	1185605	0.067	0.089	98.39
12.84	1148131	0.071	0.095	98.26
12.88	1112002	0.074	0.100	98.12
12.91	1077163	0.078	0.105	97.98
12.94	1043562	0.080	0.109	97.83
12.98	1011149	0.085	0.116	97.67
13.01	979877	0.088	0.121	97.51
13.04	949701	0.093	0.128	97.34
13.08	920575	0.098	0.135	97.16

Retention Time (min)	Molecular Weight	Intensity (mV)	d(Weight) / d Log(MW)	Weight %
13.11	892461	0.103	0.142	96.97
13.14	865317	0.107	0.148	96.78
13.18	839106	0.112	0.156	96.57
13.21	813792	0.118	0.166	96.35
13.24	789340	0.124	0.175	96.12
13.28	765716	0.128	0.182	95.88
13.31	742889	0.136	0.193	95.63
13.34	720828	0.142	0.203	95.37
13.38	699504	0.149	0.213	95.10
13.41	678889	0.155	0.223	94.81
13.44	658957	0.160	0.232	94.52
13.48	639681	0.168	0.244	94.21
13.51	621038	0.176	0.256	93.88
13.54	603003	0.183	0.267	93.54
13.58	585554	0.192	0.281	93.19
13.61	568670	0.198	0.291	92.82
13.64	552329	0.206	0.305	92.44
13.68	536512	0.214	0.318	92.05
13.71	521200	0.224	0.332	91.63
13.74	506375	0.234	0.349	91.20
13.78	492018	0.243	0.364	90.75
13.81	478113	0.253	0.380	90.28
13.84	464644	0.262	0.395	89.80
13.88	451595	0.273	0.412	89.30
13.91	438952	0.283	0.429	88.77
13.94	426700	0.294	0.447	88.23
13.98	414824	0.306	0.467	87.66
14.01	403314	0.318	0.487	87.07
14.04	392154	0.331	0.508	86.46
14.08	381334	0.342	0.526	85.83
14.11	370841	0.355	0.548	85.17
14.14	360664	0.368	0.569	84.49
14.18	350793	0.382	0.592	83.78
14.21	341216	0.397	0.617	83.05
14.24	331925	0.411	0.641	82.29
14.28	322909	0.426	0.666	81.50
14.31	314159	0.440	0.688	80.69
14.34	305666	0.456	0.715	79.85
14.38	297422	0.469	0.738	78.98
14.41	289418	0.484	0.763	78.08
14.44	281646	0.498	0.787	77.16
14.48	274099	0.514	0.813	76.21
14.51	266769	0.529	0.840	75.23
14.54	259650	0.543	0.863	74.22
14.58	252734	0.559	0.890	73.19
14.61	246015	0.574	0.916	72.12
14.64	239486	0.590	0.944	71.03
14.68	233141	0.604	0.968	69.91
14.71	226976	0.619	0.993	68.76

Retention Time (min)	Molecular Weight	Intensity (mV)	d(Weight) / d Log(MW)	Weight %
18.01	14907	0.022	0.030	1.63
18.04	14449	0.021	0.029	1.59
18.08	14003	0.020	0.028	1.56
18.11	13569	0.019	0.026	1.52
18.14	13147	0.018	0.025	1.48
18.18	12736	0.018	0.024	1.45
18.21	12336	0.018	0.024	1.42
18.24	11947	0.018	0.024	1.38
18.28	11569	0.019	0.025	1.35
18.31	11201	0.018	0.024	1.31
18.34	10843	0.017	0.023	1.28
18.38	10495	0.017	0.023	1.25
18.41	10157	0.017	0.022	1.22
18.44	9827	0.018	0.023	1.18
18.48	9508	0.016	0.020	1.15
18.51	9197	0.017	0.022	1.12
18.54	8895	0.016	0.021	1.09
18.58	8601	0.015	0.019	1.06
18.61	8316	0.014	0.017	1.04
18.64	8039	0.014	0.017	1.01
18.68	7770	0.014	0.018	0.99
18.71	7508	0.013	0.017	0.96
18.74	7254	0.013	0.016	0.94
18.78	7008	0.013	0.016	0.91
18.81	6769	0.013	0.016	0.89
18.84	6536	0.012	0.015	0.87
18.88	6311	0.012	0.015	0.84
18.91	6092	0.013	0.016	0.82
18.94	5880	0.014	0.016	0.79
18.98	5674	0.013	0.016	0.77
19.01	5475	0.013	0.016	0.74
19.04	5281	0.014	0.016	0.72
19.08	5093	0.014	0.016	0.69
19.11	4911	0.014	0.017	0.67
19.14	4735	0.014	0.017	0.64
19.18	4564	0.014	0.016	0.61
19.21	4399	0.014	0.017	0.59
19.24	4238	0.014	0.016	0.56
19.28	4083	0.013	0.015	0.54
19.31	3932	0.013	0.015	0.51
19.34	3787	0.012	0.014	0.49
19.38	3646	0.013	0.015	0.46
19.41	3509	0.012	0.014	0.44
19.44	3377	0.011	0.012	0.42
19.48	3249	0.012	0.013	0.40
19.51	3126	0.012	0.013	0.38
19.54	3006	0.011	0.012	0.36
19.58	2891	0.012	0.013	0.33
19.61	2779	0.011	0.012	0.31

Retention Time (min)	Molecular Weight	Intensity (mV)	d(Weight) / d Log(MW)	Weight %
19.64	2671	0.010	0.011	0.29
19.68	2566	0.010	0.011	0.27
19.71	2466	0.010	0.011	0.26
19.74	2368	0.010	0.010	0.24
19.78	2274	0.009	0.009	0.22
19.81	2183	0.010	0.010	0.20
19.84	2096	0.010	0.011	0.18
19.88	2011	0.010	0.010	0.16
19.91	1929	0.009	0.009	0.15
19.94	1850	0.008	0.008	0.13
19.98	1775	0.007	0.007	0.12
20.01	1701	0.006	0.006	0.11
20.04	1631	0.005	0.005	0.10
20.08	1563	0.004	0.004	0.09
20.11	1497	0.003	0.003	0.08
20.14	1434	0.002	0.002	0.08
20.18	1373	0.002	0.002	0.07
20.21	1314	0.000	0.000	0.07
20.24	1258	0.000	0.000	0.07
20.28	1204	0.001	0.001	0.07
20.31	1151	0.002	0.002	0.07
20.34	1101	0.001	0.001	0.06
20.38	1053	0.001	0.001	0.06
20.41	1006	0.002	0.002	0.06
20.44	962	0.003	0.002	0.05
20.48	919	0.003	0.003	0.05
20.51	877	0.002	0.002	0.04
20.54	838	0.003	0.003	0.04
20.58	800	0.003	0.003	0.03
20.61	763	0.003	0.002	0.03
20.64	728	0.003	0.003	0.02
20.68	695	0.004	0.003	0.01
20.71	662	0.003	0.002	0.01
20.74	631	0.003	0.002	0.00
20.78	602	0.002	0.002	0.00

Retention Time (min)	Molecular Weight	Intensity (mV)	d(Weight) / d Log(MW)	Weight %
14.74	220983	0.634	1.018	67.58
14.78	215157	0.649	1.044	66.38
14.81	209493	0.663	1.069	65.15
14.84	203987	0.677	1.092	63.89
14.88	198632	0.689	1.113	62.62
14.91	193425	0.701	1.135	61.31
14.94	188361	0.714	1.156	59.99
14.98	183435	0.726	1.178	58.64
15.01	178643	0.736	1.196	57.27
15.04	173981	0.745	1.212	55.88
15.08	169446	0.755	1.228	54.48
15.11	165032	0.760	1.238	53.06
15.14	160738	0.767	1.250	51.63
15.18	156558	0.772	1.259	50.20
15.21	152490	0.776	1.266	48.75
15.24	148530	0.777	1.270	47.30
15.28	144675	0.778	1.272	45.85
15.31	140923	0.778	1.273	44.40
15.34	137269	0.776	1.269	42.95
15.38	133711	0.772	1.264	41.50
15.41	130247	0.768	1.257	40.07
15.44	126874	0.762	1.247	38.65
15.48	123588	0.753	1.232	37.24
15.51	120388	0.743	1.217	35.85
15.54	117271	0.733	1.201	34.47
15.58	114234	0.720	1.180	33.12
15.61	111276	0.708	1.159	31.79
15.64	108394	0.693	1.135	30.49
15.68	105586	0.678	1.109	29.22
15.71	102850	0.662	1.083	27.98
15.74	100184	0.644	1.054	26.77
15.78	97586	0.627	1.025	25.59
15.81	95054	0.609	0.996	24.45
15.84	92587	0.590	0.963	23.34
15.88	90182	0.571	0.931	22.26
15.91	87838	0.551	0.898	21.23
15.94	85553	0.531	0.865	20.23
15.98	83326	0.511	0.832	19.26
16.01	81155	0.491	0.798	18.34
16.04	79038	0.470	0.763	17.45
16.08	76975	0.450	0.730	16.60
16.11	74963	0.430	0.697	15.79
16.14	73002	0.411	0.666	15.02
16.18	71089	0.393	0.636	14.28
16.21	69225	0.374	0.605	13.57
16.24	67406	0.356	0.574	12.90
16.28	65633	0.338	0.545	12.26
16.31	63905	0.323	0.519	11.65
16.34	62219	0.305	0.490	11.07

Retention Time (min)	Molecular Weight	Intensity (mV)	d(Weight) / d Log(MW)	Weight %
16.38	60575	0.290	0.464	10.52
16.41	58972	0.276	0.442	10.00
16.44	57408	0.262	0.418	9.51
16.48	55884	0.249	0.397	9.04
16.51	54397	0.236	0.376	8.59
16.54	52946	0.223	0.353	8.17
16.58	51532	0.210	0.334	7.77
16.61	50153	0.198	0.314	7.39
16.64	48808	0.187	0.296	7.04
16.68	47496	0.178	0.280	6.70
16.71	46216	0.167	0.263	6.39
16.74	44969	0.158	0.248	6.09
16.78	43752	0.149	0.233	5.80
16.81	42565	0.141	0.221	5.54
16.84	41407	0.133	0.207	5.29
16.88	40279	0.126	0.195	5.05
16.91	39178	0.117	0.182	4.83
16.94	38104	0.111	0.171	4.62
16.98	37057	0.104	0.161	4.42
17.01	36037	0.097	0.149	4.23
17.04	35041	0.090	0.138	4.06
17.08	34070	0.086	0.131	3.90
17.11	33124	0.082	0.125	3.75
17.14	32201	0.077	0.118	3.60
17.18	31301	0.073	0.111	3.46
17.21	30423	0.069	0.104	3.33
17.24	29567	0.065	0.098	3.21
17.28	28733	0.061	0.092	3.09
17.31	27920	0.058	0.087	2.98
17.34	27127	0.055	0.082	2.88
17.38	26355	0.051	0.076	2.78
17.41	25601	0.049	0.072	2.69
17.44	24867	0.046	0.068	2.60
17.48	24152	0.043	0.064	2.52
17.51	23454	0.041	0.061	2.44
17.54	22774	0.039	0.057	2.37
17.58	22112	0.036	0.053	2.30
17.61	21466	0.034	0.050	2.24
17.64	20837	0.032	0.047	2.18
17.68	20225	0.031	0.045	2.12
17.71	19628	0.029	0.042	2.06
17.74	19046	0.029	0.041	2.01
17.78	18479	0.028	0.039	1.96
17.81	17928	0.027	0.038	1.90
17.84	17390	0.025	0.035	1.86
17.88	16867	0.025	0.035	1.81
17.91	16357	0.024	0.034	1.76
17.94	15861	0.025	0.034	1.72
17.98	15377	0.023	0.033	1.67

USA-R-15307

FINAL REPORT

Mutagenicity Test of
by using Microorganisms

November 10, 2015

UBE SCIENTIFIC ANALYSIS LABORATORY, INC.

GLP STATEMENT

UBE Scientific Analysis Laboratory, Inc.

Sponsor :
Title : Mutagenicity Test of by using Microorganisms
Study code number: USA-R-15307

This test was conducted according to the Joint Notification Yakusyoku 0331 No.8 of the Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, H23・03・29 seikyoku No.6 of the Manufacturing Industries Bureau, Ministry of Economy, Trade and Industry, kanpoki No.110331010 of the Environmental Policy Bureau, Ministry of the Environment (March 31, 2011) and the Joint Notification Yakusyoku 0331 No.7 of the Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, H23・03・29 seikyoku No.5 of the Manufacturing Industries Bureau, Ministry of Economy, Trade and Industry, kanpoki No.110331009 of the Environmental Policy Bureau, Ministry of the Environment (March 31, 2011) and the Notification of Ministry of the Labour, No.76, September 1, 1988 and No.13 (revised), March 29, 2000 and the Notification of Ministry of the Labour, No.77, September 1, 1988 and No.67 (revised), June 2, 1997.

I, the undersigned, hereby declare that this report provides an accurate and faithful record of the results obtained.

Study Director Junichi Hashimoto November 10, 2015
Junichi Hashimoto

Quality Assurance Certificate

Study Facility : UBE Scientific Analysis Laboratory, Inc.

Location : 1978-6, Aza-Okinoyama, Oaza-Kogushi, Ube-shi, Yamaguchi Prefecture, Japan

Study title : Mutagenicity Test of by using Microorganisms

Study code number : USA-R-15307

Date of review or inspection	Review or inspection items	Date reported to facility manager	Date reported to study director
October 6, 2015	Study protocol	October 6, 2015	October 6, 2015
October 14, 2015	Study Preculture of bacterial strains Preparation of test article solution Preparation of test solutions and positive controls Pre-incubation and plating	October 14, 2015	October 14, 2015
October 16, 2015	Study Plate observation and count of colonies	October 16, 2015	October 16, 2015
November 10, 2015	Final report	November 10, 2015	November 10, 2015

The captioned study was audited or inspected by the person in charge of the quality assurance unit (individual responsible for quality assurance) of UBE Scientific Analysis Laboratory, Inc. according to the above schedule, and results were reported to the facility manager and the study director.

I hereby certify that the test was conducted according to the Notification Yakusyoku 0331 No.8 of the Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, H23・03・29 seikyoku No.6 of the Manufacturing Industries Bureau, Ministry of Economy, Trade and Industry, kanpoki No.110331010 of the Environmental Policy Bureau, Ministry of the Environment (March 31, 2011) and the Notification of Ministry of the Labor, Japan, No.76, September 1, 1988 and No.13 (revised), March 29, 2000, that the methods and procedures used in the test are described precisely in the final report, the final report contains accurate description of study methods and accurately reflects raw data that were obtained in compliance with the study protocol and the standard operating procedures.

November 10, 2015

Yukitsuro Noguchi

Person in charge of Quality Assurance Unit
(Individual Responsible for Quality Assurance)

CONTENTS

SUMMARY

This study was designed to assess the mutagenic potential of using a bacterial/microsome test system.

Salmonella typhimurium strains TA98, TA100, TA1535, TA1537 and *Escherichia coli* WP2*uvrA* were treated with the test material using the pre-incubation method at six dose levels, in duplicate, both with and without the addition of a rat liver homogenate metabolizing system (10% liver S9 in standard co-factors). The dose range for the dose-determination test was 4.88 to 5000 µg/plate. The experiment was repeated on a separate day using the dose range, 156 to 5000 µg/plate, fresh cultures of the bacterial strains and fresh test material formulations.

Cytotoxicity to bacteria by the test material was not observed for TA98, TA100, TA1535, TA1537 or WP2*uvrA* at any dose level with or without metabolic activation in the dose-determination test and the mutagenicity test.

Precipitate of the test material was observed for TA98, TA100, TA1535, TA1537 and WP2*uvrA* at 5000 µg/plate without metabolic activation in the dose-determination test and the mutagenicity test.

No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, at any dose level either with or without metabolic activation.

The test material was considered to be non-mutagenic under the conditions of this test.

1. TITLE

Mutagenicity Test of by using Microorganisms

2. SPONSOR

3. TESTING FACILITY

UBE Scientific Analysis Laboratory, Inc.
1978-6, Aza-Okinoyama, Oaza-Kogushi, Ube-shi, Yamaguchi Prefecture, Japan

4. PURPOSE OF TEST

Purpose of this test is to evaluate the mutagenicity of by the microbial mutagenicity test using *Salmonella typhimurium* and *Escherichia coli*.

5. TESTING METHOD

This test was conducted according to the Joint Notification Yakusyoku 0331 No.7 of the Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, H23・03・29 seikyoku No.5 of the Manufacturing Industries Bureau, Ministry of Economy, Trade and Industry, kanpoki No.110331009 of the Environmental Policy Bureau, Ministry of the Environment (March 31, 2011) and the Notification of Ministry of the Labour, No.77, September 1, 1988 and No.67 (revised), June 2, 1997.

6. GLP COMPLIANCE

This test was conducted according to the Joint Notification Yakusyoku 0331 No.8 of the Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, H23・03・29 seikyoku No.6 of the Manufacturing Industries Bureau, Ministry of Economy, Trade and Industry, kanpoki No.110331010 of the Environmental Policy Bureau, Ministry of the Environment (March 31, 2011) and the Notification of Ministry of the Labour, No.76, September 1, 1988 and No.13 (revised), March 29, 2000.

7. PERIOD OF STUDY

Commencement of Study:	October 6, 2015
Initiation of Dose-determination Test:	October 14, 2015
Initiation of Mutagenicity Test:	October 20, 2015
Completion of Study:	November 10, 2015

8. ARCHIVES

The study protocol, raw data, recorded documents, final report, documents pertaining to quality assurance, test material, and other study-related documents will be retained in the archives according to the standard operation procedure of UBE Scientific Analysis Laboratory Inc. for 10 years after receiving the notification under Article 4, Section 1 or Section 2, Article 5, Section 2, 3 or 8, Article 10, Section 3, or Article 14, Section 2 of Act on the Evaluation of Chemical Substances and Regulation of Their Manufacturing, etc., or for 10 years after submission under Article 57-3, Section 1 of Industrial Safety and Health Law, whichever is longer (the specific storage period is to be decided 10 years after the study completion upon deliberation with the sponsor).

9. AUTHOR OF FINAL REPORT AND PERSONS CONCERNED WITH TEST

Study Director: Junichi Hashimoto November 10, 2015

Junichi Hashimoto

Person in charge of Test Material: Shigemitsu Yano

Personnel in concerned: Shigemitsu Yano

Yumi Kikuta

10. MATERIALS AND METHODS

10.1 Test Material

Name of the new chemical substance:

Other name :

Structural formula:

Lot No.	:
Purity of the new chemical substance tested	: ≥99%
Concentration of impurities	: <1% Water
CAS No.	:
Molecular weight	:
Appearance at ordinary temperature	:
Stability	: Stable at room temperature
Degree of solubility	: Water; <50 g/L (*) : DMSO; >50 g/L (*) : Acetone; soluble : THF; soluble

* Test result at UBE Scientific Analysis Laboratory

10.2 Tester Strains

Salmonella typhimurium TA100, TA1535, TA98 and TA1537
Escherichia coli WP2*uvrA*

All of the strains were obtained from Dr. T. Matsushima, Japan Bioassay Research Center, Japan Industrial Safety And Association, Hadano-shi, Kanagawa. All of the strains were stored at -80°C. Prior to the master strains being used, characterization checks were carried out to confirm the amino-acid requirement, presence of rfa, R factor, *uvrB* or *uvrA* mutation and the spontaneous reversion rate.

In this assay, overnight sub-cultures of the appropriate coded stock cultures were prepared in nutrient broth and incubated at 37°C for 7 hours. Each culture was monitored spectrophotometrically for turbidity determined by viable count analysis on nutrient agar plates.

10.3 Preparation of Test and Control Materials

Test Material:

The test material was not soluble in water at 50 mg/ml, but was soluble in DMSO at 50 mg/ml in solubility checks performed in-house. Therefore, DMSO was selected as the vehicle of choice. The test material was dissolved in DMSO to make a stock solution of 50 mg/ml and further diluted to obtain desired concentrations. Purity conversion was not made in the preparation.

Positive control Materials:

A solvent treatment group was used as the vehicle control and the positive control materials were as follows:

2-(2-Furyl)-3-(5-nitro-2-furyl)acrylamide (AF-2, Wako Pure Chemical, Lot # STQ3987):
AF-2 at 0.1 μg/50 μl/plate for TA98
AF-2 at 0.01 μg/50 μl/plate for TA100 and WP2*uvrA*
Sodium azide (NaN_3, Wako Pure Chemical, Lot # YSF7467): 0.5 μg/50 μl/plate for TA1535
9-Aminoacridine (9-AA, MERCK, Lot # S03761): 80 μg/50 μl/plate for TA1537

In addition, 2-aminoanthracene (2-AA, Wako Pure Chemical, Lot # CTK0326), which is non-mutagenic in the absence of metabolizing enzymes, was used in the series of plates with S9 mix at the following concentrations:

2-AA at 0.5 μg/50 μl/plate for TA98
2-AA at 1.0 μg/50 μl/plate for TA100
2-AA at 2.0 μg/50 μl/plate for TA1535 and TA1537
2-AA at 10 μg/50 μl/plate for WP2*uvrA*

10.4 Microsomal Enzyme Fraction

S9 was purchased from Oriental Yeast Co., Ltd. S9 (Lot No.15071704) was prepared on July 17, 2015 from the livers of male Sprague-Dawley rats weighing 210.1 ± 10.0 g (Mean ± S.D.). These had each intraperitoneally injected phenobarbital (PB, 4 times 0.03-0.06 g/kg/day) and 5,6-benzoflavone (BF, 1 time 0.08 g/kg/day) prior to S9 separation. The S9 was stored at -80°C.

10.5 S9 mix and Agar

The S9 mix was prepared immediately before use using sterilized co-factors and maintained on ice for the duration of the test.

Constituents	Amount in 1ml S9 mix
S9	0.1 ml
$MgCl_2$	8 μmol
KCl	33 μmol
Glucose-6-phosphate	5 μmol
NADPH	4 μmol
NADH	4 μmol
Na-phosphate Buffer (pH 7.4)	100 μmol

A 0.5 ml aliquot of S9 mix and 2 ml of molten, trace histidine and biotin or tryptophan supplemented, top agar were overlaid onto a sterile Vogel-Bonner Minimal agar plate in order to assess the sterility of the S9 mix. This procedure was repeated on the day of each experiment.

Top agar was prepared using 0.6% Difco Bacto agar and 0.5% sodium chloride with 10 ml of 0.5 mM histidine and 0.5 mM biotin or 0.5 mM tryptophan solution added to each 100 ml of top agar. Vogel-Bonner Minimal agar plates were purchased from Kyokuto Pharmaceutical Industrial Co., Ltd.

10.6 Test Procedure

10.6.1 Dose-Determination test

Six concentrations of the test material (4.88, 19.5, 78.1, 313, 1250 and 5000 μg/plate) were assayed in duplicate against each tester strain, using the pre-incubation method.

Measured aliquots (0.1 ml) of the test material formulation, vehicle or positive control (0.05 ml) were dispensed into sets of test tubes followed by either 0.5 ml of S9 mix or phosphate buffer, 0.1 ml of one of the bacterial cultures. The contents of each test tube were incubated at 37°C for 20 min. and mixed with 2.0 ml of molten, trace histidine and biotin or tryptophan supplemented, top agar and evenly distributed onto the surface of Vogel-Bonner Minimal agar plates (one tube per plate). This procedure was repeated, in duplicate, for each bacterial strain and for each concentration of test material both with and without S9 mix.

After 48 hours incubation at 37°C, all of the plates were assessed for numbers of revertant colonies using a colony analyzer CA-11S (System Science Co., Ltd.) or manually.

10.6.2 Mutagenicity test

The second experiment was performed using methodology as described for the dose-determination test, using fresh bacterial cultures, test material and control solutions. The test material dose range was between 156 and 5000 μg/plate both with and without S9 mix.

10.7 Evaluation Criteria

The test material was considered mutagenic if the following criteria were met.

1 The number of revertants at one or more doses was equal to or greater than twice that with the negative.control.
2 In the above case, there was a dose-related increase in the number of revertants.
3 The results were reproducible in two separate tests.

11. RESULTS AND DISCUSSION

The individual plate counts, the mean number of revertant colonies for the test material, vehicle and positive controls both with and without metabolic activation, are presented in Appendix 1 and Appendix 2.

Cytotoxicity to bacteria by the test material was not observed for TA98, TA100, TA1535, TA1537 or WP2*uvrA* at any dose level with or without metabolic activation in the dose-determination test and the mutagenicity test.

Precipitate of the test material was observed for TA98, TA100, TA1535, TA1537 and WP2*uvrA* at 5000 μg/plate without metabolic activation in the dose-determination test and the mutagenicity test.

No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains at any dose level, either with or without metabolic activation.

The test material was considered to be non-mutagenic under the conditions of this test.

All of the positive control chemicals used in the test induced marked increases in the frequency of revertant colonies thus confirming the activity of the S9 mix and the sensitivity of the bacterial strains.

12. REFERENCES

[1] Ames, B. N., McCann, J. and Yamasaki, E. (1975). Methods for detecting carcinogens and mutagens with the Salmonella/mammalian-microsome mutagenicity test. *Mutation Res.*, **31**, 347-364.

[2] Matsushima, T., Sawamura, M., Hara, K. and Sugimura, T. A safety substitute for polychlorinated biphenyls as an inducer of metabolic activation system. In: de Serres, F. J., Fouts., J. R., Bend, J.R. and Philpot, R. M. (Eds), (1976). *In vitro Metabolic Activation in Mutagenesis Testing*, Elsevier, Amsterdam, pp. 85-88

[3] Maron, D. and Ames, B. N. (1983) Revised methods for the Salmonella mutagenicity test. *Mutation Res.*, **113**, 173-215.

Appendix 1

Test Results (Dose-determination test)

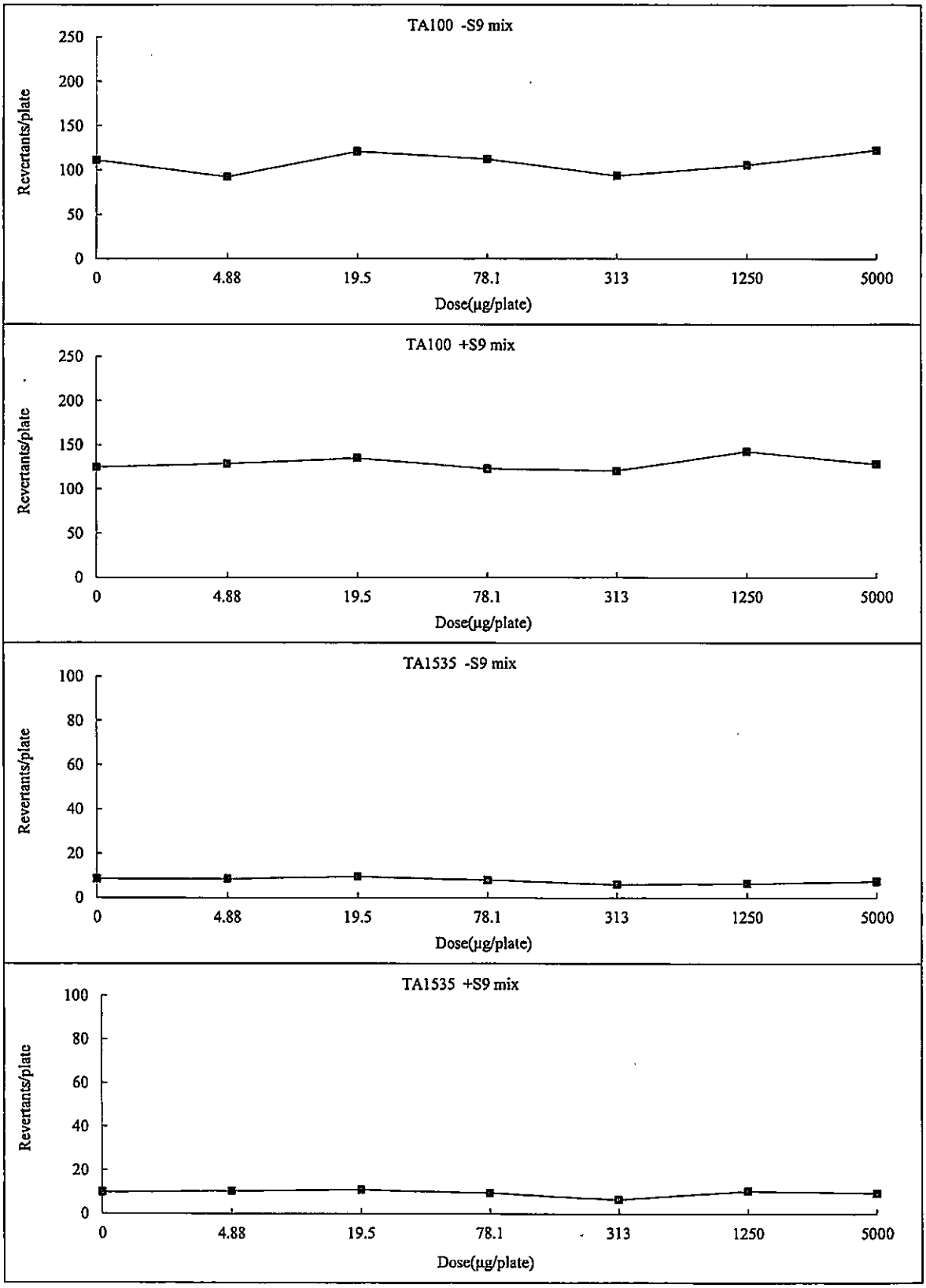
Name of Test Material:

Test period		From October 14, 2015 to October 16, 2015									
With(+) or Without(-) S9 mix	Test material dose (μg/plate)	Number of revertants (Number of colonies/plate)									
		Base-pair substitution type						Frame-shift type			
		TA100		TA1535		WP2*uvrA*		TA98		TA1537	
-S9 mix	Negative control	116	(112)	9	(9)	11	(17)	24	(27)	6	(6)
		107		8		22		30		6	
	4.88	96	(92)	4	(9)	18	(19)	25	(24)	6	(6)
		88		13		19		23		6	
	19.5	118	(121)	9	(10)	24	(25)	22	(25)	8	(9)
		124		10		25		27		10	
	78.1	107	(113)	8	(8)	22	(20)	20	(25)	3	(6)
		118		8		18		29		9	
	313	104	(94)	9	(6)	18	(19)	19	(23)	6	(7)
		83		3		19		27		8	
	1250	97	(106)	3	(7)	18	(19)	20	(18)	8	(6)
		114		10		19		15		4	
	5000†	136	(123)	2	(8)	22	(20)	19	(18)	8	(9)
		109		13		18		17		10	
+S9 mix	Negative control	136	(125)	9	(10)	20	(25)	30	(32)	14	(12)
		114		11		30		34		10	
	4.88	122	(129)	10	(11)	20	(20)	28	(31)	13	(16)
		135		11		19		34		19	
	19.5	135	(135)	9	(11)	22	(21)	27	(25)	14	(12)
		135		13		20		22		9	
	78.1	113	(123)	13	(10)	16	(22)	28	(30)	14	(14)
		133		6		27		32		14	
	313	120	(121)	8	(7)	17	(23)	30	(30)	5	(9)
		121		5		28		29		13	
	1250	152	(143)	10	(11)	23	(30)	20	(23)	11	(14)
		133		11		37		26		16	
	5000	127	(129)	12	(10)	30	(26)	34	(27)	11	(14)
		130		7		22		19		16	
Positive control not requiring S9 mix	Name	AF-2 [1]		NaN_3 [2]		AF-2		AF-2		9-AA [3]	
	Dose (μg/plate)	0.01		0.5		0.01		0.1		80	
	Number of colonies/plate	739	(697)	324	(338)	152	(158)	647	(668)	277	(292)
		655		352		163		689		306	
Positive control requiring S9 mix	Name	2-AA [4]		2-AA		2-AA		2-AA		2-AA	
	Dose (μg/plate)	1.0		2.0		10		0.5		2.0	
	Number of colonies/plate	1760	(1768)	455	(484)	971	(1032)	555	(551)	256	(247)
		1775		512		1093		547		237	

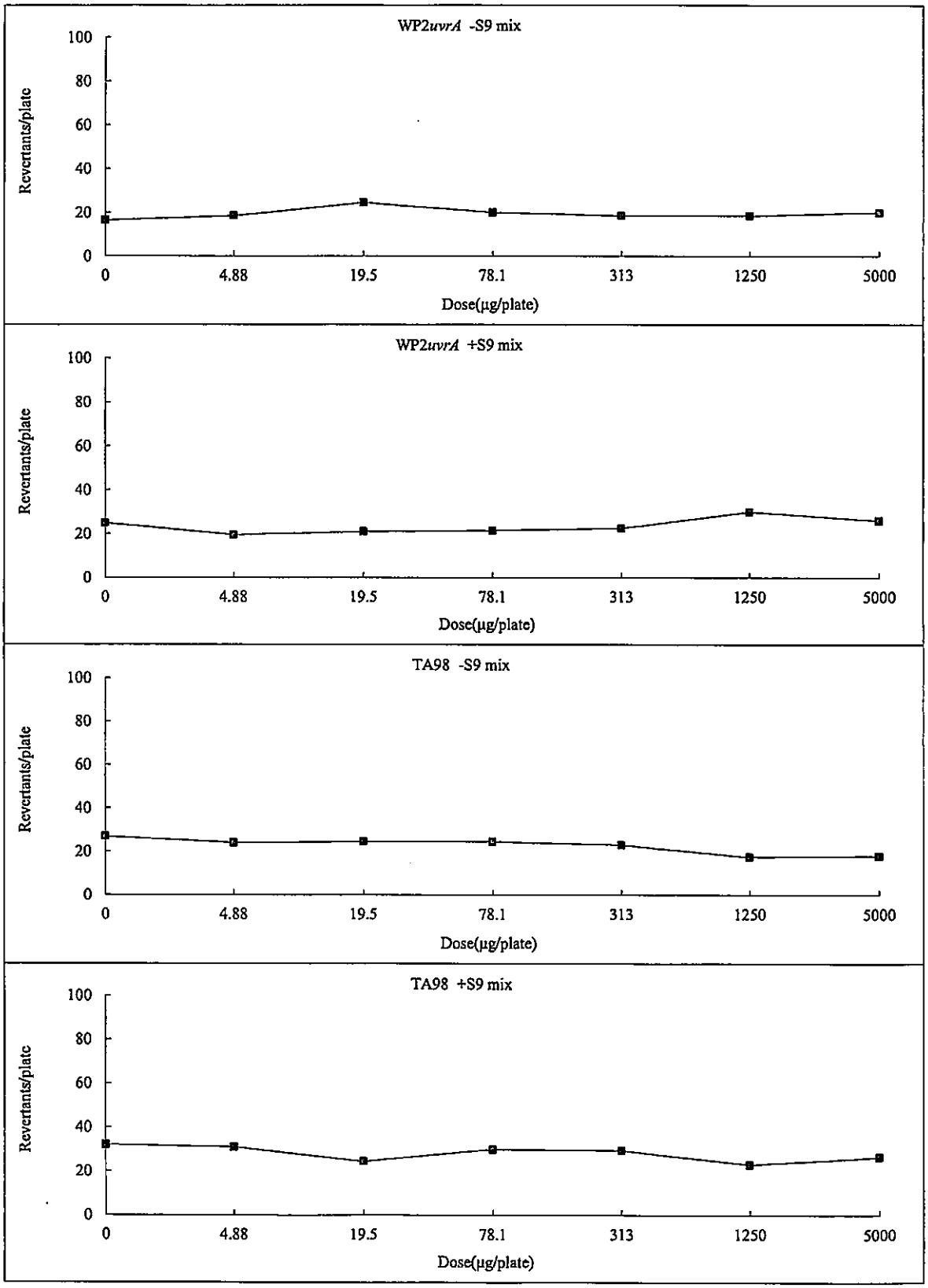
1)AF-2 :2-(2-Furyl)-3-(5-nitro-2-furyl)acrylamide
2)NaN_3 :Sodiumazide
3)9-AA :9-Aminoacridine
4)2-AA :2-Aminoanthracene

[Notes]
1. When cytotoxicity was observed, "*" was placed to the right of the number of the revertants.
2. When precipitation was observed, "†" was placed to the right of the test substance dose.
3. The average number of revertants in each dose was shown in ( ).

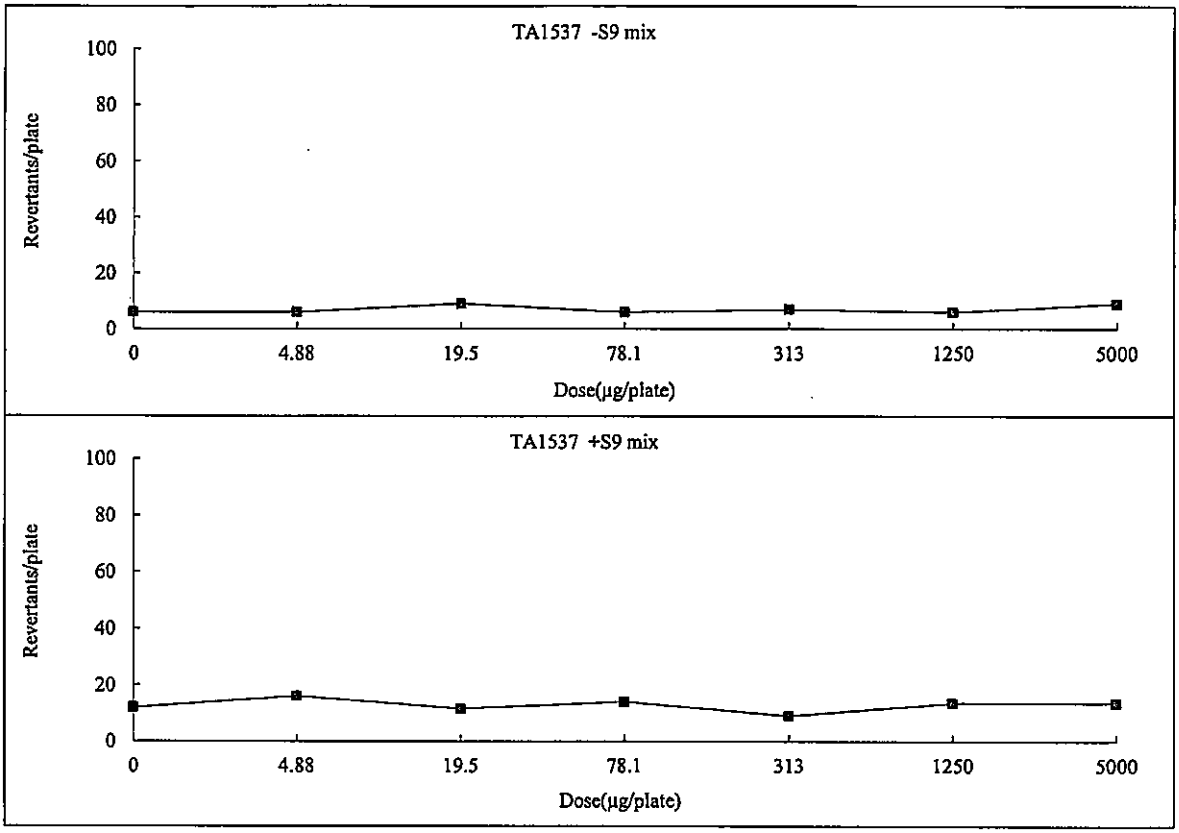
Dose-response curves (Dose-determination test)



Dose-response curves (Dose-determination test)



Dose-response curves (Dose-determination test)



Appendix 2

Test Results (Mutagenicity test)

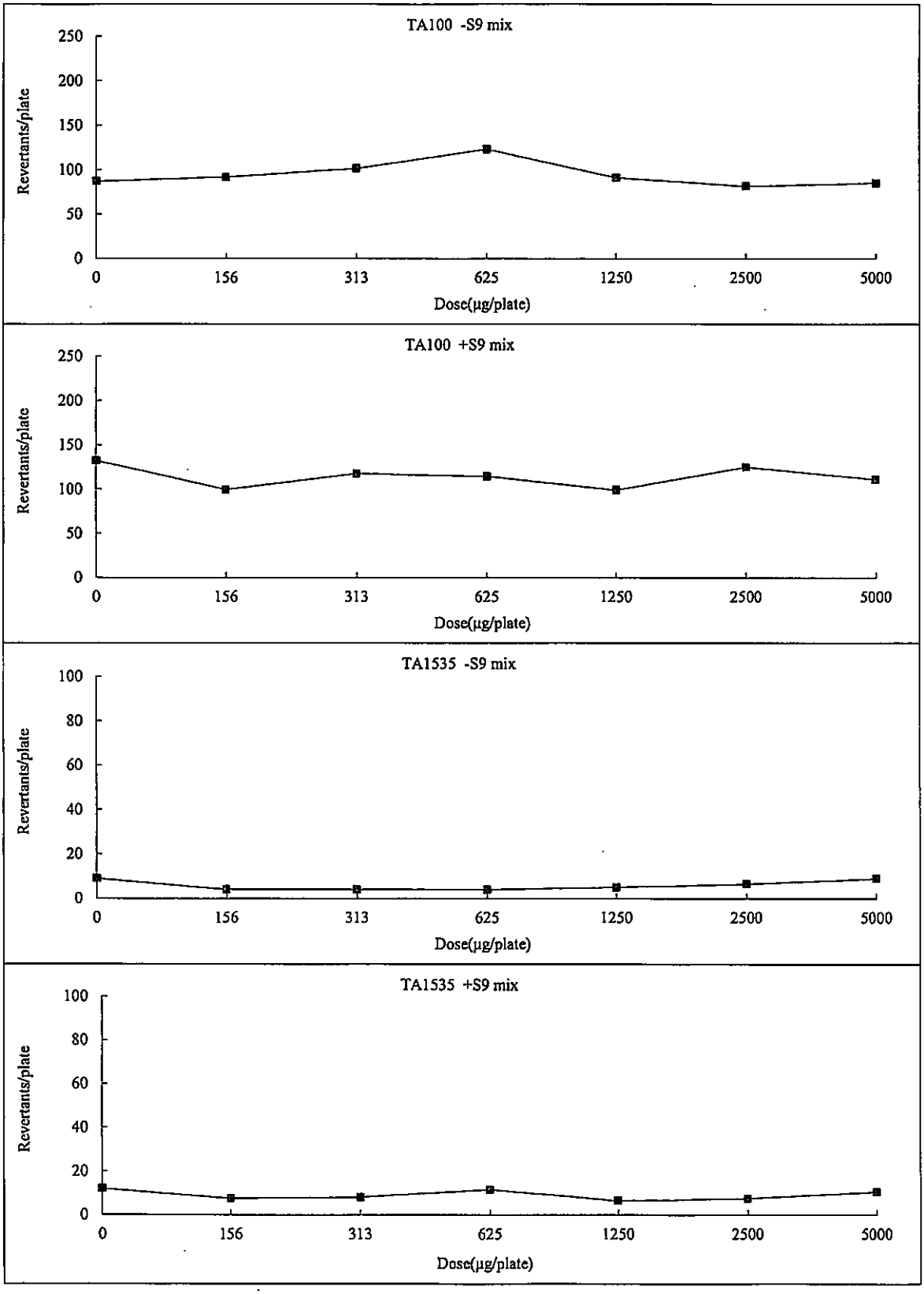
Name of Test Material:

Test period		From October 20, 2015 to October 22, 2015									
With(+) or Without(-) S9 mix	Test material dose (μg/plate)	Number of revertants (Number of colonies/plate)									
		Base-pair substitution type						Frame-shift type			
		TA100		TA1535		WP2*uvrA*		TA98		TA1537	
-S9 mix	Negative control	95	(87)	10	(9)	18	(21)	27	(25)	6	(10)
		79		8		24		22		13	
	156	92	(92)	4	(4)	27	(28)	15	(17)	13	(12)
		91		4		28		19		11	
	313	114	(102)	5	(4)	20	(26)	13	(19)	5	(7)
		89		3		32		25		9	
	625	127	(123)	3	(4)	18	(22)	24	(20)	8	(8)
		119		5		26		16		8	
	1250	93	(91)	6	(5)	22	(23)	19	(24)	8	(6)
		89		4		23		28		3	
	2500	87	(82)	5	(7)	32	(23)	19	(17)	6	(5)
		76		8		13		15		4	
	5000†	86	(85)	11	(9)	30	(24)	12	(16)	6	(6)
		84		7		18		20		5	
+S9 mix	Negative control	122	(132)	14	(12)	42	(36)	19	(22)	10	(15)
		142		10		30		24		19	
	156	95	(100)	10	(8)	33	(29)	25	(22)	14	(13)
		104		5		25		18		11	
	313	89	(118)	8	(8)	30	(32)	27	(25)	10	(12)
		146		8		34		23		14	
	625	126	(115)	5	(12)	33	(31)	28	(26)	9	(13)
		103		18		28		23		16	
	1250	104	(99)	9	(7)	28	(24)	18	(25)	9	(9)
		94		4		20		32		9	
	2500	126	(125)	5	(8)	33	(31)	32	(26)	16	(13)
		124		10		29		19		9	
	5000	110	(111)	11	(11)	22	(27)	28	(23)	14	(14)
		112		10		32		18		14	
Positive control not requiring S9 mix	Name	AF-2 [1]		NaN_3 [2]		AF-2		AF-2		9-AA [3]	
	Dose (μg/plate)	0.01		0.5		0.01		0.1		80	
	Number of colonies/plate	812	(784)	358	(364)	237	(221)	648	(608)	431	(457)
		756		370		205		567		482	
Positive control requiring S9 mix	Name	2-AA [4]		2-AA		2-AA		2-AA		2-AA	
	Dose (μg/plate)	1.0		2.0		10		0.5		2.0	
	Number of colonies/plate	1852	(1803)	416	(436)	860	(944)	524	(523)	284	(263)
		1753		456		1028		521		242	

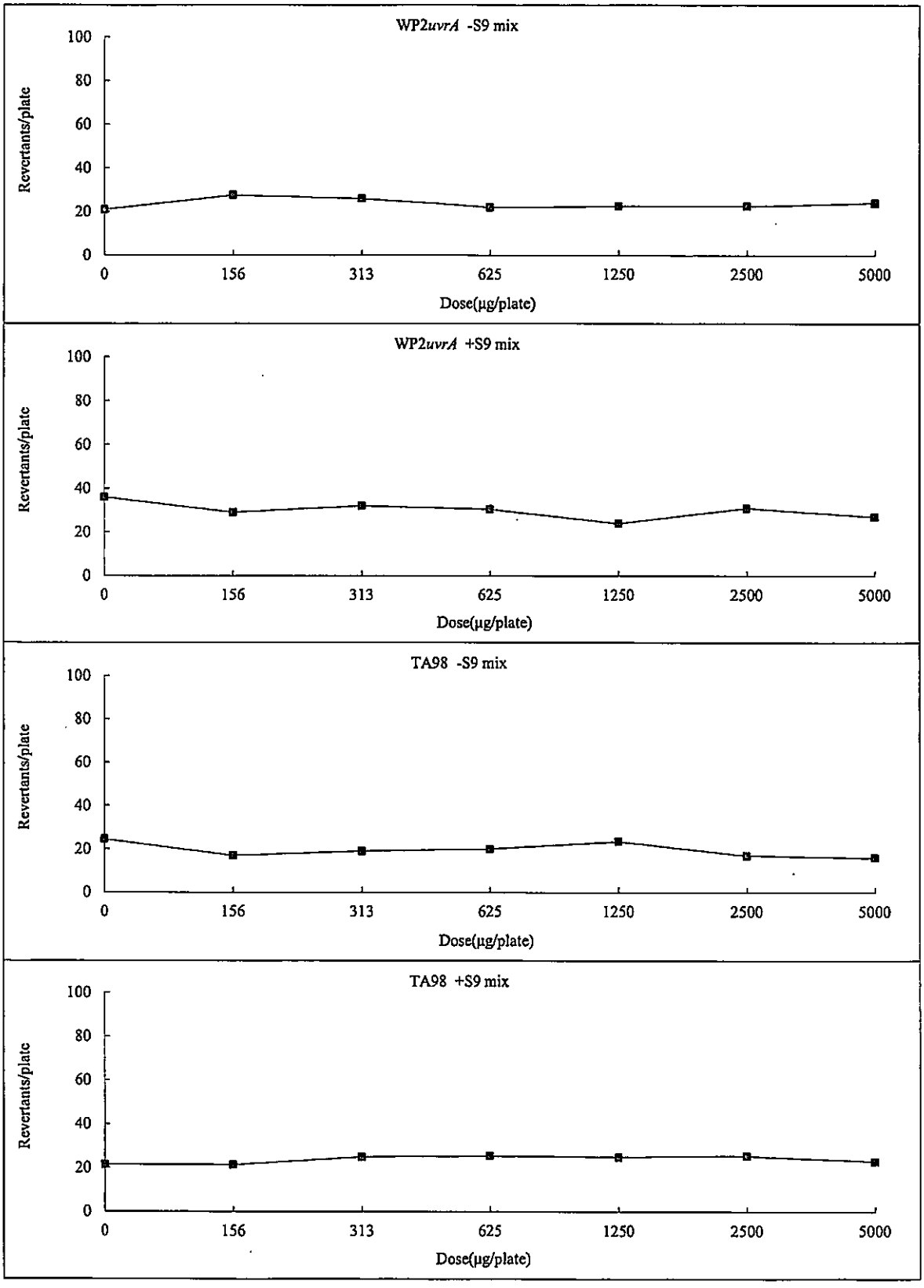
1)AF-2 :2-(2-Furyl)-3-(5-nitro-2-furyl)acrylamide
2)NaN_3 :Sodiumazide
3)9-AA :9-Aminoacridine
4)2-AA :2-Aminoanthracene

[Notes]
1. When cytotoxicity was observed, "*" was placed to the right of the number of the revertants.
2. When precipitation was observed, "†" was placed to the right of the test substance dose.
3. The average number of revertants in each dose was shown in ( ).

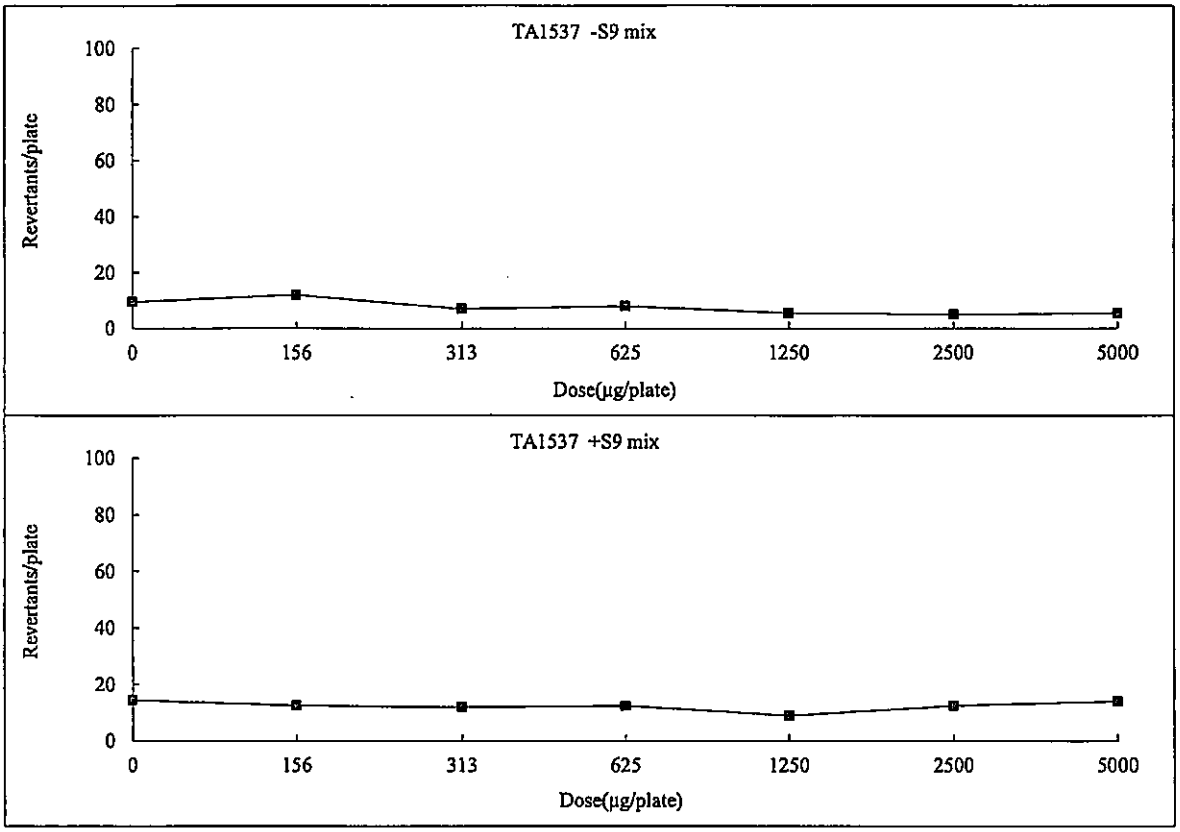
Dose-response curves (Mutagenicity test)



Dose-response curves (Mutagenicity test)



Dose-response curves (Mutagenicity test)



Process Flow Sheet ( )